

*Implant manual*

ELA **ovatio**  **CRT**

**Model 6750**  
**Implantable cardioverter defibrillator**

 **SORIN GROUP**  
AT THE HEART OF MEDICAL TECHNOLOGY



Model 6750

WEB 01/04V

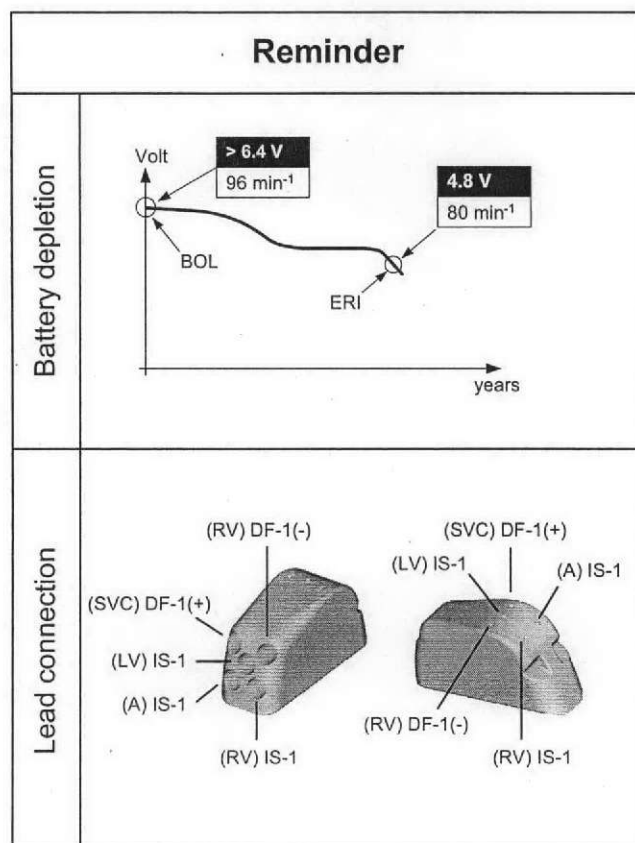
### **IMPLANT MANUAL**

Implantable cardioverter defibrillator  
Biventricular antitachycardia pacing  
Dual chamber arrhythmia detection  
DDDR biventricular pacing

**CAUTION: Federal law restricts this device to sale by or on the order of a physician.**

The OVATIO model described in this manual is covered by the following US patents:

5 271 394, 5 411 533, 5 462 060, 5 818 703, 5 564 430, 5 513 645,  
5 645 574, 5 674 265, 5 741 315, 5 891 184, 5 899 931, 5 167 224,  
5 226 415, 5 339 820, 5 350 406, 5 325 856, 5 312 451, 6 307 261,  
5 591 218, 5 558 097, 5 626 619, 5 545 181, 5 697 960,  
5 702 426, 5 702 424, 5 713 928, 5 776 164, 5 776 165, 5 836 980,  
5 891 170, 5 868 793, 5 935 153, 5 931 856, 5 954 660, 5 978 708,  
6 236 111, 6 256 206, 6 181 968, 6 337 996, 6 532 238, 6 230 058,  
6 251 703, 6 397 105, 6 408 209, 6 487 451, 6 505 068, 6 487 452.



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## 1. GENERAL DESCRIPTION

OVATIO CRT-D 6750 is an implantable cardioverter defibrillator for the recognition and treatment of ventricular tachycardia and fibrillation, with ventricular resynchronization, in patients with spontaneous or inducible tachyarrhythmias. OVATIO CRT-D 6750 is equipped with an accelerometer to allow adaptation of pacing to suit the patient's activity.

## 2. INDICATIONS

OVATIO CRT-D 6750 is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening arrhythmias.

The device is also indicated for the reduction of heart failure symptoms in medically optimized NYHA Functional Class III and IV patients with left ventricular ejection fraction of 35% or less, and a QRS duration of 150 ms or longer.

## 3. CONTRAINDICATIONS

Implantation of OVATIO CRT-D 6750 is contraindicated in patients:

- whose ventricular tachyarrhythmias may have transient or reversible causes such as: acute myocardial infarction, digitalis intoxication, drowning, electrocution, electrolyte imbalance, hypoxia, sepsis, or unstable ischemic episodes,
- who present incessant tachyarrhythmia,
- who have an internal pacemaker,
- whose primary disorder is bradyarrhythmias, or atrial tachyarrhythmias,

Dual-chamber and single chamber atrial pacing is contraindicated in patients with chronic refractory atrial tachyarrhythmias.

#### 4. WARNINGS AND PRECAUTIONS

The patient should be warned of the potential risks of defibrillator malfunction if he is exposed to external magnetic, electrical, or electromagnetic signals.

These potential interference sources may cause conversion to inhibited mode (because of noise detection), erratic delivery of VT or VF therapies, nominal programming, or much more rarely, irreversible damage to the device's circuits.

The main sources of high magnitude electrical interference are: powerful radiofrequency equipment (radar), industrial motors and transformers, induction furnaces, resistance and arc-welding equipment, and high power loudspeakers.

Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT) which may result in non-conversion of the arrhythmia post-operatively. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

**Resuscitation Availability.** Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

**Electrical Isolation.** Do not permit the patient to contact grounded equipment that could produce hazardous leakage current. Ensuing arrhythmia induction could result in the patient's death.

**Disable the ICD During Handling.** Program Shock Therapy to OFF during surgical implant and explant or post mortem procedures. The device can deliver a serious high energy shock should accidental contact be made with the defibrillation electrodes.

**Antitheft gates.** Since antitheft devices at the entrance to stores are not subject to any safety standards, it is advisable to spend as little time as possible in their vicinity.



**Airport detection systems.** Since airport detection systems are not subject to any safety standards, it is advisable to spend as little time as possible in their vicinity.

**High voltage power transmission lines.** High voltage power transmission lines may generate enough EMI to interfere with defibrillator operation if approached too closely.

**Communication equipment.** Communication equipment such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate enough EMI to interfere with defibrillator operation if approached too closely.

**Home appliances.** Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with defibrillator operation. There are reports of device disturbances caused by electric hand tools or electric razors used directly over the device implant site.

**Cellular phones.** Radiofrequency signals can interfere with the functioning of OVATIO CRT-D 6750 if the handset is placed too close to the defibrillator. It is advisable to maintain a minimum distance of 30 cm (12 inches) between the cellular telephone and the implanted device, when the telephone is turned on.

**CAUTION :** Do not tap sharply on the ICD can after implant, because the ICD's sensing circuits can detect this as P-waves or R-waves, and such oversensing could result in inappropriate pacing, inhibition, or therapy. Normal activities after implant do not result in such oversensing.

#### **4.1. RISKS RELATED TO MEDICAL ENVIRONMENT**

It is advisable to carefully monitor defibrillator operation prior to and after any medical treatment during which an electrical current from an external source passes through the patient's body.

**Magnetic Resonance Imaging.** MRI is strictly contraindicated in cardiac defibrillator patients.

**Radiofrequency ablation.** A radio frequency ablation procedure in a patient with a generator may cause device malfunction or damage. RF ablation risks may be minimized by: 1. Programming Shock Therapy and ATP to OFF. 2. Avoiding direct contact between the ablation catheter and the implanted lead or generator. 3. Positioning the ground, placing it so that the current pathway does not pass through or near the device, i.e. place the ground plate under the patient's buttocks or legs. 4. Having external defibrillation equipment available.

**Electrocautery or diathermy device.** Diathermy and electrocautery equipment should not be used. If such devices must be used: 1. Keep the current path and ground plate as far away from the device and the leads as possible (a minimum of 15 cm [six inches]). 2. Before procedure, deactivate ATP and shock therapies. 3. During the procedure, keep the electrocautery device as far as possible from the cardiac defibrillator. Set it at minimum intensity. Use it briefly. 4. After the procedure, check for proper implant function. The device should never be exposed directly to the diathermy source.

**External defibrillation.** OVATIO CRT-D 6750 is protected from external defibrillation shocks. Before external defibrillation, deactivate ATP and shock therapies. During external defibrillation, it is advisable to avoid placing the defibrillating paddles directly over the casing or over the leads. The defibrillating paddles should preferably be placed in an anteroposterior position. Avoid any direct contact between the defibrillation paddles and the conductive parts of the implanted leads or casing of the implanted device. After external defibrillation, check for proper device function.

**Radiation therapy.** Avoid exposure to ionizing radiation. Betatrons are contraindicated. If high doses of radiation therapy cannot be avoided, the defibrillator should be protected from direct exposure with a screen. ATP and shock therapies should be disabled during exposure and proper device function should be checked regularly afterwards. Resulting damage may not be immediately detectable. If irradiation of tissues close to the implantation site is necessary, it is

recommended that the cardiac defibrillator be moved. As a safety measure, an external defibrillator should be immediately available.

**Lithotripsy.** Lithotripsy may permanently damage the device if it is at the focal point of the lithotripsy beam. If lithotripsy must be used, keep the defibrillator at least 2.5 to 5 cm (1-2 inches) away from the focal point of the lithotripsy beam.

**Diagnostic ultrasound (echography).** The defibrillator is not affected by ultrasound imaging devices.

**Scales with body fat monitors and electronic muscle stimulators.** A patient with an implanted OVATIO CRT-D 6750 should not use these devices.

## **4.2. STERILIZATION, STORAGE AND HANDLING**

**Restertilization.** Do not restertilize and re-implant explanted ICDs.

**"Use Before" Date.** A "Use Before" date is printed on the outer storage package and on the sterile package. Do not implant the device after this date because the battery may have reduced longevity and sterility may be affected. It should be returned to ELA Medical.

**If Package Is Damaged.** Do not use the device or accessories if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to the manufacturer.

**Device Storage.** Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage. Store the device between 0 - 50 °C (32 - 122 °F). Temperatures outside the specified range may damage the device.

**Equilibration.** Allow the device to reach room temperature before programming or implanting the device because rapid temperature changes may affect initial device function.

### 4.3. IMPLANTATION AND DEVICE PROGRAMMING

Use only an ELA Medical programmer to communicate with the device.

Do not inadvertently position any magnet over the ICD; this suspends tachyarrhythmia detection and treatment.

Replace the device when the programmer displays an ERI and a battery voltage of  $4.80 \pm 0.01$  V or a magnet rate lower than or equal to 80 bpm.

Program device parameters such as sensitivity threshold and VT and VF detection intervals as specified in the device manuals.

**Lead System.** Do not use a lead system other than those with demonstrated compatibility because undersensing cardiac activity and failure to deliver necessary therapy may result.

In situations where an ICD and a pacemaker are implanted in the same patient, interaction testing should be completed. If the interaction between the ICD and the pacemaker cannot be resolved through repositioning of the leads or reprogramming of either the pacemaker or the ICD, the pacemaker should not be implanted (or should be explanted if previously implanted).

Failure to properly insert the torque screwdriver into the perforation at an angle perpendicular to the connector receptacle may result in damage to the sealing system and its self-sealing properties.

A safety margin of at least 10 J in the defibrillation threshold (DFT) has been recommended by some implanters and may be beneficial. Carefully confirm that true ventricular fibrillation has been induced because the DFT for ventricular tachycardia or flutter may be lower.

The defibrillator should be implanted with the engraved side facing outwards in order to facilitate telemetric communication with the programming head and to display the radiographic identification correctly.

#### **4.4. LEAD EVALUATION AND LEAD CONNECTION**

OVATIO CRT-D 6750 has two DF-1 and three IS-1 connector ports. IS-1 refers to the international standard whereby leads and generators from different manufacturers are assured a basic fit (ISO 5841-1:1992). DF-1 refers to the international standard for defibrillation lead connectors (ISO 11318:1993).

Do not tie a ligature directly to the lead body, tie it too tightly, or otherwise create excessive strain at the insertion site as this may damage the lead. Use the lead stabilizer to secure the lead lateral to the venous entry site.

With the exception of Situs OTW, which requires mineral oil for IS-1 sleeve installation, do not immerse the leads in mineral oil, silicone oil, or any other liquid.

Do not grip the lead with surgical instruments.

Do not use excessive force or surgical instruments to insert a stylet into a lead.

Use ventricular transvenous leads with caution in patients with either a mechanical or bioprosthetic tricuspid valvular prosthesis.

Use the correct suture sleeve (when needed) for each lead, to immobilize the lead and protect it against damage from ligatures.

Never implant the system with a lead system that has a measured shock impedance of less than 30 ohms. A protection circuit in the defibrillator prevents shock delivery when impedance is too low. If the shock impedance is less than 30 ohms, reposition the lead system to allow a greater distance between the electrodes.

Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

Do not insert a lead connector pin into the connector block without first visually verifying that the setscrews are sufficiently retracted. Do not tighten the setscrews unless a lead connector pin is inserted because it could damage the connector block.

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Lead electrodes in contact during a cardioversion or defibrillation therapy will cause current to bypass the heart, possibly damaging the ICD and the leads. While the ICD is connected to the leads, make sure that the metal portions of any electrodes do not touch each other.

If a pacing lead is abandoned rather than removed, it must be capped to ensure that it is not a pathway for currents to or from the heart.

If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.

Do not place the patch lead over nerve tissue as this may cause nerve damage.

Place the patch lead with the conducting coil side facing the heart to ensure delivery of energy to the heart.

Place the sutures well outside the coil of the patch lead or in the area between the coils to avoid possible coil fracture.

If countershock is unsuccessful using external paddles, adjust the external paddle position (e.g., anterior-lateral to anterior-posterior) and be sure that the external paddle is not positioned over the patch.

Do not fold, alter, or remove any portion of the patch as it may compromise electrode function or longevity.

If a header port is unused on the generator, the port must be plugged to protect the generator.

#### **4.5. GENERATOR EXPLANT AND DISPOSAL**

Interrogate the device, and program shock therapy off prior to explanting, cleaning or shipping the device to prevent unwanted shocks.

Return all explanted generators and leads to the manufacturer.

Never incinerate the device due to the potential for explosion. The device must be explanted before cremation.

## **5. ADVERSE EVENTS**

Clinical data presented in this section are from the MSP clinical study. Ovatio CRT-D is similar in design and function to the Alto 2 MSP devices. The data provided are applicable to Ovatio CRT-D.

### **5.1. MSP STUDY**

ELA Medical conducted an international, multi-center, randomized clinical trial of its cardiac resynchronization therapy system. Investigators attempted to implant study devices in 190 patients. A total of 182 patients received study devices and had an exposure of over 165 device years. Of those patients, 19 received Ovatio CRT-D, 160 received Alto 2 MSP, and 3 received Alto MSP. The clinical data collected on Alto and Alto 2 MSP are applicable to Ovatio CRT-D. The table below summarizes the adverse events observed for the CRT-D system. No deaths were related to the system.

Event	# of Patients	% of Patients	# of Events	Events/100 Device-Years*
Deaths not related to the system	16	8.4	16	0.8
Cardiac arrest	5	2.6	5	0.3
Worsening CHF / CHF decompensation	3	1.6	3	0.2
Multi-organ dysfunction	2	1.1	2	0.1
Complications related to the system	28	14.7	35	2.1
Dislodgment or migration	9	4.7	11	0.6
Extracardiac stimulation (e.g., phrenic stim)	9	4.7	9	0.5
Complications related to the implant procedure	18	9.5	21	1.3
Dislodgment or migration	4	2.1	4	0.2
Observations related to the system	23	12.1	27	1.7
Extracardiac stimulation (e.g., phrenic stim)	12	7.9	15	0.8
Observations related to the implant procedure	24	12.6	28	1.7
Heart block	6	3.2	6	0.3
Extracardiac stimulation (e.g., phrenic stim)	3	1.5	5	0.3
Serious adverse events not related to the system	85	44.7	176	10.8
Worsening CHF/CHF decompensation	24	12.6	42	2.1
Atrial fibrillation/flutter	14	7.4	14	0.7
Not Serious events not related to the system	58	30.5	121	7.4
Pain (in back, arms, chest, shoulder, groin, head, other)	10	5.3	13	0.7
Worsening CHF/CHF decompensation	13	6.8	16	0.8
Atrial fibrillation/flutter	7	3.7	8	0.4
Ventricular tachycardia	7	3.7	7	0.4

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## 5.2. POTENTIAL ADVERSE EVENTS

Adverse events (in alphabetical order), including those reported in the previous tables, associated with ICD systems include:

- Acceleration of arrhythmias (caused by device),
- Air embolism,
- Bleeding,
- Chronic nerve damage,
- Erosion,
- Excessive fibrotic tissue growth,
- Extrusion,
- Fluid accumulation,
- Formation of hematomas or cysts,
- Inappropriate shocks,
- Infection,
- Keloid formation,
- Lead abrasion and discontinuity,
- Lead migration/dislodgment,
- Myocardial damage,
- Pneumothorax,
- Shunting current or insulating myocardium during defibrillation with internal or external paddles,
- Potential mortality due to inability to defibrillate or pace,
- Thromboemboli,
- Venous occlusion,
- Venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD system that may include the following:

- Dependency,
- Depression,
- Fear of premature battery depletion,
- Fear of shocking while conscious,
- Fear that shocking capability may be lost,
- Imagined shocking (phantom shock).

## **6. CLINICAL STUDIES**

Clinical data presented in this section are from the MSP clinical study. Ovatio CRT-D is similar in design and function to the Alto 2 MSP devices. The data provided are applicable to Ovatio CRT-D.

### **6.1. MSP CLINICAL STUDY**

Ovatio CRT-D and earlier models were evaluated clinically in an international, multi-center, randomized clinical trial of ELA Medical's cardiac resynchronization therapy (CRT-D) system. Investigators attempted to implant study devices in 190 patients. A total of 182 patients received study devices and had an exposure of over 165 device years. Of those patients, 19 received Ovatio CRT-D, 160 received Alto 2 MSP, and 3 received Alto MSP.

**Objectives.** The primary objectives of the study were to demonstrate:

- Greater improvement in a composite endpoint (percent improvement in peak VO<sub>2</sub> percent improvement in quality of life) for CRT-D patients than for control patients.
- System complication-free rate  $\geq 67\%$  at six months.

**Methods.** Patients were New York Heart Association class III or IV and had one or more indications for an implantable cardioverter defibrillator (ICD). Patients performed cardiopulmonary exercise testing at baseline and six-months after randomization. Patients were implanted with an ELA Medical ICD with CRT-D, a Situs UW28D left ventricular lead, and commercially available right atrial and ventricular leads. Routine follow-ups were at pre-discharge, randomization (3-14 days post-implant), one month, three months, and six months post randomization.

## Results

### IMPROVEMENT IN COMPOSITE ENDPOINT

Patients were included in the analysis if complete (peak VO<sub>2</sub> and quality of life) baseline and six-month data were available.

Number of patients contributing to analysis	Mean percent improvement in composite endpoint for control group	Mean percent improvement in composite endpoint for CRT-D group	Percent greater improvement for CRT-D group	p-value
132	15.5 %	24.9 %	9.4 %	0.046

### SIX-MONTH SYSTEM COMPLICATION-FREE RATE

Number of patients contributing to analysis	Kaplan-Meier six-month complication-free estimate	One-sided lower 95% confidence bound for six-month complication-free estimate
190	89.5 %	84.1 %

#### ♦ 6.1.1. Absolute Differences in Peak VO<sub>2</sub> and QOL

The tables below show the absolute differences between the control and test groups' peak VO<sub>2</sub> and QOL over the 6 month follow-up period in the clinical trial.

Absolute difference between test and control groups' change in peak VO<sub>2</sub> over 6 months

		Baseline Mean ± SD (range)	6-month Mean ± SD (range)	Difference within group	Difference between groups
Change in Peak VO <sub>2</sub>	Control group (n=41)	13.39 ± 4.58 (5.02, 24.10)	13.12 ± 3.99 (3.30, 20.70)	- 0.28	1.85
	Test group (n=91)	11.84 ± 3.90 (3.50, 26.31)	13.41 ± 4.28 (6.18, 27.67)	1.57	

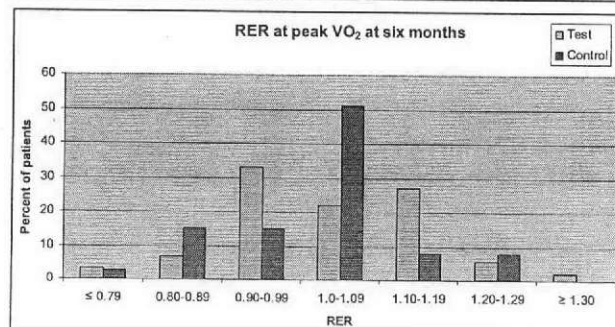
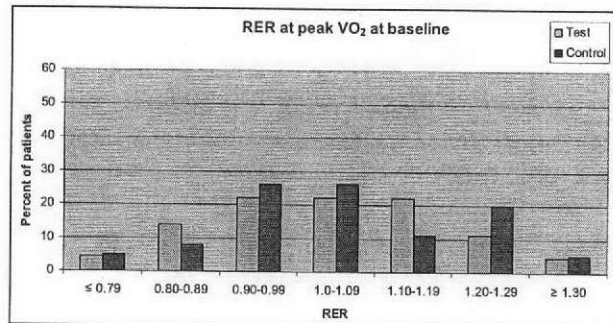
Absolute difference between test and control groups' change in QOL score over 6 months

		Baseline Mean ± SD (range)	6-month Mean ± SD (range)	Difference within group	Difference between groups
Change in QOL	Control group (n=41)	47.5 ± 19.29 (9, 90.3)	31.21 ± 23.96 (0, 95)	16.29	1.28
	Test group (n=91)	52.81 ± 21.84 (9, 92)	35.24 ± 23.73 (0, 93)	17.57	

The table below presents the percentage of patients in each group who improved, worsened, or remained unchanged in each element of the composite score and the composite score itself.

	QOL score		VO2 Score		Composite Score	
	Control Group	Test Group	Control Group	Test Group	Control Group	Test Group
% Improved	75.6	74.7	48.8	67.0	62.2	70.9
% Worsened	24.4	25.3	51.2	31.9	37.8	28.6
% Unchanged	0.0	0.0	0.0	1.1	0.0	0.0

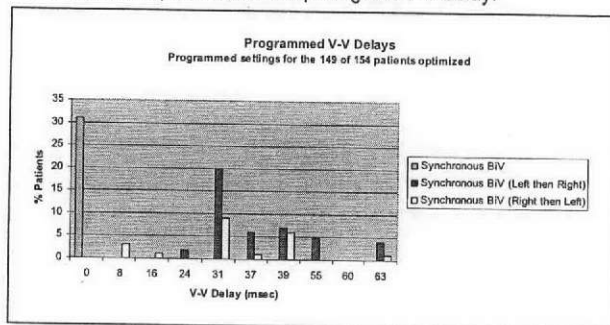
Histograms for RER at peak VO<sub>2</sub> at baseline and 6 month follow-up are provided below :



#### ◆ 6.1.2. Clinical Results V-V timing

V-V programmable settings were available for the clinical study devices as follows: Alto MSP model 617 (not programmable for V-V delay), Alto 2 MSP model 627 values (0, 31, 39, 47, 55 and 63 ms) and Ovatio CRT-D model 6750 values (0 to 63 ms in steps of 8 ms).

The graph below shows the programmed V-V settings at randomization by percentage of patients programmed to each combination of Synchronous BiV pacing and V-V delay.



The optimization protocol in the clinical study specified that each patient randomized should undergo echo guided V-V optimization. Per the investigational plan for the MSP Clinical Trial, a uniform protocol was used for V-V programming. This protocol required all patients to undergo echo-guided V-V delay optimization before randomization (2 to 14 days post-implant). The optimal V-V delay was determined by finding the programmable V-V delay and ventricular chamber pacing order ((RV then LV, or LV then RV) providing the maximum time velocity integral (TVI or VTI) across the left ventricular outflow tract (LVOT).

Only those patients randomized to the Test arm were required to be programmed per the optimization protocol for the V-V delay.

Of the 177 patients that presented at randomization, 3 had Model 617 which does not have V-V programmability hence the inability to optimize. Of the remaining 174 patients, 154 (89%) were tested per the V-V optimization protocol. One hundred forty-nine (149) of the 154 patients who were tested per the V-V optimization protocol were programmed per the recommended or randomized V-V delay (97%). Thirty-one (31) patients were programmed to BiV synchronous (V-V delay 0ms), 46 were programmed to Sequential BiV (LV then RV), 22 were programmed to Sequential (RV then LV), and the remaining 50 patients were randomized to RV only.

A sub-analysis of the composite endpoint comparing the subset of CRT-D patients with optimized V-V delays vs. the subset of patients that did not undergo V-V delay optimization demonstrated similar results in both groups. The CRT-D patients who did not undergo V-V delay optimization showed a smaller improvement in the composite endpoint, although the sample size did not permit conclusions based on data from this subset.

## **6.2. PRE-CLINICAL TESTS ON OVATIO**

The OVATIO design is the latest in a series of successive refinements in ELA's implantable cardioverter defibrillator line. The changes made to create OVATIO are not major changes in device function for which additional clinical data are necessary to demonstrate safety and effectiveness. The changes were made to address rare events, provide features already available on other ELA marketed devices, and provide minor enhancements to device operation. Therefore, in addition to structured testing of all software demonstrating that specific CRT-D functions operate as intended, the company conducted tape and unstructured testing to demonstrate the device operates as intended. The tests performed are described below.

The following test results are applicable to Ovatio DR 6550 and Ovatio CRT-D 6750 because both models have the same functioning:

- during detection of ventricular signals: this is because the left ventricular lead has no effect on the sensing functions and because the VV delay is forced to 0 ms within the arrhythmia detection zones,
- during shock therapy because CRT-D functions have no effect on this therapy.

#### ◆ 6.2.1. Tape testing

**Methods.** A series of tests was performed to evaluate ventricular arrhythmia detection in OVATIO with respect to that in Alto 2 using recorded electrograms. The objective was to verify that the detection of ventricular signals during ventricular fibrillation and tachycardia was at least as good as that observed in Alto 2.

The company injected cardiac signals from recorded electrograms into the device and monitored Alto 2 and OVATIO behavior in response to each rhythm. An ELA electrogram library and the Ann Arbor Electrogram Library were used. The libraries included 25 supraventricular tachycardias (SVT), 18 ventricular tachycardias (VT), and 61 ventricular fibrillations (VF).

#### **Results.**

##### *AS-SHIPPED SETTINGS IN OVATIO VS. AS-SHIPPED SETTINGS IN ALTO 2*

Devices were programmed to their as-shipped settings. As-shipped settings are identical in both devices except that OVATIO has a Fast VT detection zone (200 bpm) and values are rounded in OVATIO. (See section "Programmable parameters" for as-shipped settings.) Devices were tested using VT, SVT, and VF electrograms.



For rhythms in the VT zone, both OVATIO and Alto 2 correctly classified all VT rhythms (100 % sensitivity). Both devices misclassified 2 SVT rhythms as VT (92 % specificity).

For rhythms in the VF zone, both OVATIO and Alto 2 correctly classified all VF rhythms (100 % sensitivity).

#### *PARAD+ TEMPLATE IN OVATIO VS. PARAD+ TEMPLATE IN ALTO 2*

Devices were programmed to their as-shipped settings except that the tachy sorting template was programmed to PARAD+ in both devices. Devices were tested using VT and SVT electrograms.

For rhythms in the VT zone, both OVATIO and Alto 2 correctly classified all VT rhythms (100 % sensitivity). Both devices misclassified one SVT rhythm as VT (96 % specificity).

#### ◆ 6.2.2. Unstructured testing

**Methods.** A series of unstructured tests were performed using a proprietary cardiac simulator and observation system. The objective of this testing was to determine if particular requirements for a specific intended use can be consistently fulfilled.

The ICD sends signals to the simulator like it does to a human heart and the simulator sends signals back to the device. The simulator is able to generate normal and pathological rhythms. Many device features can be evaluated at one time. Test rhythms were designed to evaluate the pacing and defibrillation features that differ from the previous ICD.

**Results.** A total of 94 tests were performed to evaluate pacing functions and 39 for defibrillation functions. Rhythms simulated were bradycardia (without and without conduction disorders), sinus tachycardia, supraventricular tachycardia, and ventricular tachycardia. All tests showed that the pacing and defibrillation features operated as intended.

## 7. PATIENT SELECTION AND TREATMENT

### 7.1. INDIVIDUALIZATION OF TREATMENT

**Exercise stress testing.** If the patient's condition permits, use exercise stress testing to:

- Determine the maximum rate of the patient's normal rhythm,
- Identify any supraventricular tachyarrhythmias,
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

*CAUTION : When a parameter is reprogrammed during an exercise stress test, PARAD/PARAD+ algorithm forces acceleration to "ventricular". During conducted sinus tachycardia within the programmed Tachy zone, the device detects a 1:1 fast rhythm. Assuming that acceleration was set to ventricular by reprogramming, the device concludes for a VT, and immediately applies the corresponding therapy. This event could have been avoided with appropriate device handling during tests.*

**Electrophysiologic (EP) testing.** EP testing may be useful for ICD candidates. EP testing may identify the classifications and rates of all the ventricular and atrial arrhythmias, whether spontaneous or during EP testing.

**Drug resistant supraventricular tachyarrhythmias (SVTs).** Drug resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

**Antiarrhythmic drug therapy.** If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose rather than a loading dose at the time of ICD implantation. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify ICD detection and conversion. The ICD also may need to be reprogrammed.

Changes in a patient's antiarrhythmic drug or any other medication that affects the patient's normal cardiac rate or conduction can affect the rate of tachyarrhythmias and/or efficacy of therapy.

Direct any questions regarding the individualization of patient therapy to ELA Medical's representative.

## **7.2. SPECIFIC PATIENT POPULATIONS**

**Pregnancy.** If there is a need to image the device, care should be taken to minimize radiation exposure to the fetus and the mother.

**Nursing Mothers.** Although appropriate biocompatibility testing has been conducted for this implant device, there has been no quantitative assessment of the presence of leachables in breast milk.

**Pediatric Patients.** This device has not been studied in patients younger than 18 years of age.

**Geriatric Patients.** Most (62%) of the patients receiving this device in clinical studies were over the age of 60 years.

**Handicapped and Disabled Patients.** Special care is needed in using this device for patients using an electrical wheel chair or other electrical (external or implanted) devices.

## **8. PATIENT COUNSELING INFORMATION**

The physician should consider the following points in counseling the patient about this device:

- Persons administering CPR may experience tingling on the patient's body surface when the patient's ICD system delivers a shock.
- Advise patients to carry ELA Medical ID cards and/or ID bracelets documenting their ICD system.

## **9. CONFORMANCE TO STANDARDS**

This device was developed in conformance with all or parts of the following standards:

- EN 45502-1: Active Implantable Medical Devices, General requirements for safety, marking and for information to be provided by the manufacturer, November 1998,
- ISO 5841-3: 1992, IS-1 Pacemaker Lead Connector Standard,
- ISO 11318 (DF-1): Cardiac defibrillator: connector assembly for implantable defibrillators - Dimensional and test requirements, August 2002,
- AAMI Pacemaker Standard - Labeling Requirements and Terminology for Implantable Artificial Cardiac Pacemakers. FDA Contract No. 223-74-5083. August, 1975,
- ANSI/AAMI Standard, PC69: Active Implantable Medical Devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillator, May 2000.

This information should not be used as a basis of comparisons among devices since different parts of the standards mentioned may have been used.

## 10. PHYSICIAN GUIDELINES

### 10.1. PHYSICIAN TRAINING

Physicians should be familiar with sterile pulse generator and left ventricular pacing lead implant procedures. They must apply these procedures according to professional medical training and experience.

Physicians should be familiar with follow-up evaluation and management of patients with an implantable defibrillator (or referral to such a physician).

This training guideline for implantation and follow-up of ICD and CRT-D devices comes from the Heart Rhythm Society to provide standards for hospital credentialing bodies to help ensure appropriate patient care and lead to improved patient outcomes. The following is a summary of requirements for an alternate training pathway for ICD and CRT-D implantations<sup>(1)</sup>:

- Documentation of current experience: 35 pacemaker implantations per year and 100 implantations over the prior 3 years
- Proctored ICD implantation experience: 10 Implantations, 5 Revisions
- Proctored CRT-D implantation experience: 5 implantations
- Completion of didactic course and/or IBHRE® ExAM
- Monitoring of patient outcomes and complication rates
- Established patient follow-up
- Maintenance of competence: 10 ICD and CRT-D procedures per year, 20 patients per year in follow-up

<sup>(1)</sup> Please consult full text of both publications for details. 2004 Heart Rhythm Society Clinical Competency Statement and the 2005 Addendum on Training Pathways for Implantation of Cardioverter Defibrillators and Cardiac Resynchronization Devices. *Heart Rhythm* (2004) 3, 371-375; *Heart Rhythm* (2005) 2(10), 1161-1163.

## 10.2. DIRECTIONS FOR USE

ICD operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the *Patient Registration Form* and return it to ELA Medical, as it provides necessary information for warranty purposes and patient tracking.

Additional programming instructions can be found by accessing Online Help (click the "?" on the screen) on the Orchestra programmer. Paper copies of Online Help can be obtained by contacting your ELA Medical representative.

## 10.3. MAINTAINING DEVICE QUALITY

This device is **FOR SINGLE USE ONLY**. Do not resterilize and reimplant explanted ICDs.

**Do not implant the device when:**

- It has been dropped on a hard surface because this could have damaged pulse generator components.
- Its sterility indicator within the inner package is not green, because it might not have been sterilized.
- Its storage package has been pierced or altered, because this could have rendered it non-sterile.
- It has been stored or transported outside the environmental temperature limits: 32 °F (0 °C) to 122 °F (50 °C) as an electrical reset condition may occur.
- "Use Before" date has expired, because this can adversely affect pulse generator longevity or sterility.

## 10.4. V-V PROGRAMMING RECOMMENDATION

It is recommended that V-V optimization testing be performed and used to set the V-V delay for this device to optimize the potential for CRT-D benefit to the patient.

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## **11. PATIENT INFORMATION**

Information for the patient is available in the patient booklet, contained in the outer storage package. Additional copies can be obtained by contacting your ELA Medical representative or on the ELA Medical's web site: <http://www.sorin-crm.com>. This information should be given to each patient with their first ICD and offered to the patient on each return visit or as deemed appropriate.

## **12. HOW SUPPLIED**

### **12.1. MODELS AVAILABLE**

The OVATIO defibrillator is available in three models, CRT-D 6750, DR 6550 and VR 6250. The CRT-D 6750 model accepts one unipolar lead (LV) and two bipolar leads (A and RV) with the IS-1 connector standard.

### **12.2. STERILITY**

The OVATIO defibrillator are supplied one per package in a sterile package.

### **12.3. WARRANTY AND REPLACEMENT POLICY**

ELA Medical warrants its defibrillators. Refer to the section "Warranty" for additional information. Please see the following labeling sections for information concerning the performance of this device: Indications, Contraindications, Warnings and Precautions, and Adverse Events.

### 13. DEVICE DESCRIPTION

The OVATIO CRT-D system includes the model 6750 ICD device and programming system. The programming system includes the Orchestra programmer with Elaview programming software connected to a CPR3 programming head. The programming system is configured and furnished by ELA Medical.

The OVATIO CRT-D 6750 can serve as a defibrillation electrode (active housing) with a total surface area of 64 cm<sup>2</sup>.

The OVATIO CRT-D 6750 is designed to recognize and treat slow or fast VT and VF by continuously monitoring atrial and ventricular activity to identify persistent ventricular arrhythmias and to deliver appropriate therapies. OVATIO CRT-D 6750 features the PARAD/PARAD+ algorithm, which is specifically designed to differentiate ventricular tachycardias from fast rhythms of supraventricular origin. PARAD/PARAD+ continuously monitors R-R interval stability, searches for long cycles, assesses the degree of P-R association, evaluates sudden onset and determines the chamber of arrhythmia acceleration.

In addition to the advanced detection scheme, OVATIO CRT-D 6750 offers programmable single, dual or triple-chamber pacing therapy (DDD, DDI, VVI or AAIsafeR modes) with or without rate-responsive capabilities (DDDR, VVIR, DDD/DDIR and AAIsafeRR modes) using an acceleration sensor. An automatic AV delay algorithm as well as a mode switching function are available.

OVATIO CRT-D 6750 enables an adjustment of the interventricular delay, and provides the possibility of adapting pacing to each ventricle. The ICD is intended to resynchronize uncoordinated contraction of the heart by simultaneously or sequentially pacing both ventricles.

OVATIO CRT-D 6750 offers tiered therapy. Therapies can be programmed independently in each zone:



- in the Slow VT and VT zones: two ATP programs, up to two shocks with programmable energy and up to four shocks with maximum energy can be programmed;
- in the VF zone: one ATP program, up to two shocks with programmable energy and up to four shocks with maximum energy can be programmed.

The ATP can be applied in RV, LV or RV and LV pacing with a VV delay equal to 0 ms. ATP pacing configuration is independent of ventricular pacing configuration.

When the rhythm changes from one zone to another, the device delivers the therapy programmed in this zone, starting with the same or more aggressive program for the area. The ATP program in the VF zone will only be applied if the VT coupling interval is longer than the programmed fast VT cycle length.

The OVATIO CRT-D 6750 offers biphasic shocks with a maximum stored energy of 34 J. The shock configuration (electrodes used to apply the shock) can be chosen by programming one of the following combinations: can and one coil, can and 2 coils, 2 coils only.

Other features are as follows:

- Automatic ventricular sensing threshold control
- Non-committed shocks
- Electrophysiological studies (EPS) with real-time markers or electrograms:
  - Programmer-controlled VT induction sequences,
  - Programmer-controlled VF inductions (30 Hz rapid pacing or shock on T),
  - Programmable electrogram vectors:
    - V EGM; integrated ventricular bipolar,
    - A EGM; integrated atrial bipolar,
    - V-A EGM; ventricular lead tip to atrial lead tip.
  - Real-time annotations displayed with the markers and indicating the majority rhythm,
  - Manual ATP sequences,

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- Manual shocks.
- Rescue shock
- Automatic follow-up tests:
  - Defibrillation electrode continuity,
  - Capacitor charge time,
  - Pacing lead impedance,
  - Automatic pacing threshold tests.
- Data storage
  - Therapy History Report,
  - Statistics (pace/sense, therapy, shocks, and battery voltage),
  - Up to 15 complete Holter records with event logs, marker channel notation, and electrogram records.

The connector head has five ports: atrial bipolar pace/sense, right ventricular bipolar pace/sense, left ventricular unipolar pace and two ports for RV and SVC defibrillation coils. Both pace/sense ports and the pace port are compatible with the IS-1 standard and both defibrillation ports are compatible with the DF-1 standard. Distal lead terminal connections are secured with set-screws accessed via self-sealing silicone plugs. All lead connections pass through the header into the device via ceramic feedthroughs.

**Programming System.** The ELA Medical programmer is used in conjunction with specific programmer software to interrogate and program the implanted device at implant and during patient follow-up procedures.

***Physician's manual***



# Situs **OTW**

**Left ventricular Over The Wire lead**



**SORIN GROUP**  
AT THE HEART OF MEDICAL TECHNOLOGY

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**CAUTION:** Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

#### EXPLANATION OF SYMBOLS ON PRODUCT LABELING



For single use only.



Attention: Consult accompanying documentation.



Use before



Sterilization lot number



Contents have been ethylene oxide sterilized.



Date of manufacture

**NOTE:** "Sorin Biomedica CRM S.r.l." is identified as "SORIN" in this manual.

## GENERAL DESCRIPTION

The Situs OTW is a unipolar, steroid eluting pacing lead designed to pace the left ventricle through a coronary vein. It is used in conjunction with ELA Medical congestive heart failure pulse generators.

All materials used in the manufacture of this lead have been submitted to strict testing to ensure biocompatibility.

A silicone elastomer region at the distal tip of the lead contains a maximum of 1.0 mg of dexamethasone sodium phosphate. Upon exposure to body fluids, the steroid elutes progressively into the cardiac tissue around the electrode. The steroid is intended to minimize local inflammatory response and to reduce threshold elevation during the first weeks post-implantation.

The attached technical sheet describes the technical specifications relevant to the model of lead supplied with this manual.

## INDICATION

Situs OTW is designed to pace the left ventricle through a coronary vein. It is intended to be used in conjunction with ELA Medical cardiac resynchronization therapy pulse generators.

## CONTRAINDICATION

Do not implant in patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate may be contraindicated.

**WARNING:** *The device cannot be implanted in veins with a lumen > 7 French (2.3 mm).*

## PRECAUTIONS

- A defibrillator must always be immediately available in the operating room throughout implantation of the lead.
- When implanted, the pacing lead is in direct electrical contact with the myocardium. Only battery-operated and CF powered electrical appliances should be used during the procedure.
- An AC electrical appliance that could accidentally be connected to the lead should not be placed in the vicinity of the patient.
- All operating room electrical appliances must be grounded.
- It is strongly advised not to use electrocoagulation appliances in the vicinity of an implanted lead.
- Do not immerse the lead tip in fluid prior to implantation as this may cause elution of some of the steroid and result in reducing the anti-inflammatory effect.
- Protect the carbon electrode from contact with powders, fibers and silicone oil lubricant. They may contaminate the electrode or clog the pores and therefore reduce the electrical performance.
- Radio opaque fluid should not be injected directly into the guide catheter. It is better to introduce a specific balloon catheter into the guide catheter that is already *in situ*.

- When using a right ventricular (RV) and a right atrial (RA) pace/sense leads in conjunction with the Situs OTW lead, it is recommended that a polyurethane insulated RV and RA leads be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause periodic or continual loss of pacing, or sensing, or both.

## ADVERSE EVENTS

Situs UW28D was evaluated clinically in an international, multi-center, randomized clinical trial of ELA Medical's cardiac resynchronization therapy system. Investigators attempted to implant study devices in 190 patients. There was a total exposure of over 136 device years. Of the patients implanted, 152 received Situs UW28D leads (149 at initial implant and 3 at a re-intervention). The table below summarizes the adverse events observed in patients with a Situs lead implanted. No deaths were related to the lead.

The most common complications and observations related to the lead are detailed in the table below.

Type of event	Number of patients	Percent of patients (%)	Number of events	Events per 100 device months
Deaths not related to the lead	10	6.6	10	0.6
Complications related to the lead	14	9.2	17	1.0
Most common complications:				
Dislodgment	6	3.95	7	-
Extra cardiac stimulation	7	4.6	7	-
Complications related to the implant procedure	14	9.2	17	1.0
Observations related to the lead	12	7.9	14	0.9
Most common observation:				
Extra cardiac stimulation	10	6.58	12	-
Observations related to the implant procedure	20	13.2	24	1.5
Serious adverse events not related to the lead	69	45.4	142	8.7
Not serious adverse events not related to the lead	47	30.9	99	6.1

## CLINICAL STUDIES

Situs UW28D was evaluated clinically in an international, multi-center, randomized clinical trial of ELA Medical's cardiac resynchronization therapy (CRT) system. Investigators attempted to implant study devices in 190 patients. There was a total exposure of over 136 device years. Of the patients implanted, 152 received Situs UW28D leads (149 at initial implant and 3 at a re-intervention).

### ◆ Objectives

The primary lead-related objectives of the study were to achieve:

- Six-month Situs lead complication-free rate  $\geq 67\%$
- Situs UW28D lead implant success rate  $\geq 75\%$
- Mean chronic Situs pacing threshold  $\leq 3.25$  V
- Mean chronic biventricular pacing impedance  $\geq 100\ \Omega$

### ◆ Methods

Patients were New York Heart Association class III or IV and had one or more indications for an implantable cardioverter defibrillator (ICD). Patients were implanted with a Situs UW28D left ventricular lead, an ELA Medical ICD with CRT, and commercially available right atrial and ventricular leads. Routine follow-ups were at pre-discharge, randomization (3-14 days post-implant), one month, three months and six months post randomization.

### ◆ Results

#### *SITUS SIX-MONTH COMPLICATION-FREE RATE*

Number of patients contributing to analysis	Kaplan-Meier six-month complication-free estimate	One-sided lower 95% confidence bound for six-month complication-free estimate
190	94.9 %	91.6 %

#### *SITUS IMPLANT SUCCESS RATE*

Number of patients contributing to analysis (Situs lead implant attempts)	Number of patients successfully implanted with Situs lead	Percent of patients successfully implanted with Situs lead (implant success rate)	One-sided lower 95% confidence bound for implant success rate
177	149	84 %	77.9 %



#### *SITUS CHRONIC (SIX-MONTH) PACING THRESHOLD*

Number of patients contributing to analysis	Mean chronic pacing threshold	Standard deviation of chronic pacing threshold	One-sided upper 95% confidence bound for chronic pacing threshold
98	1.83 V	1.04 V	2.00 V

#### *SITUS CHRONIC BIVENTRICULAR PACING IMPEDANCE*

Number of patients contributing to analysis	Mean chronic biventricular impedance	Standard deviation of chronic biventricular impedance	One-sided lower 95% confidence bound for chronic biventricular impedance
118	390 $\Omega$	92.1 $\Omega$	376.05 $\Omega$

### **CONTENTS OF THE PACKAGE**

#### ◆ **Sterile package**

- Pacing lead with anchoring sleeve and silicone stop
- Vein lifter
- Funnel
- Torquer
- 2 Implant stylets

#### ◆ **Non sterile documentation**

- Physician's manual
- Technical sheet
- Product identification stickers

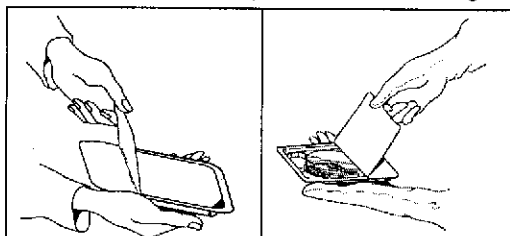
### **STORAGE**

The lead must be stored at a temperature between 0° C and 50° C (32 °F and 122 °F).

## OPENING THE PACKAGE

Carefully examine the package before opening to:

- check the use before date,
- make sure that the package has not been damaged or opened.



## STERILIZATION

All SORIN leads are sterilized with ethylene oxide before delivery.

After the use before date or in the event of alteration of the sterile package, please contact your local Sorin Group representative who will advise you what to do.

**CAUTION: Never resterilize this lead.**

## POTENTIAL ADVERSE EVENTS

Adverse events that may occur as a result of implantation of the Situs OTW are listed in alphabetical order below:

- Air embolism
- Allergic reaction
- Arrhythmia at implant
- Bleeding
- Cardiac or venous perforation
- Cardiac tamponade
- Coronary sinus or venous trauma
- Death
- Extracardiac stimulation
- Infection
- Lead conductor fracture
- Lead dislodgment
- Lead insulation break

- Lead/pulse generator connection problem
- Myocardial trauma
- Pacing threshold elevation
- Pneumothorax
- Renal failure from contrast material used to visualize coronary veins
- Transient AV block
- Venous or coronary venous occlusion

## **EQUIPMENT REQUIRED FOR IMPLANTATION**

An angioplasty stylet (0.014 in. / 0.35 mm) is required for the lead implantation.

Additional stylets are available in a re-intervention stylet kit.

*NOTE: This equipment is not contained in the lead package.*

## **PREPARING THE LEAD**

1. Inject heparinized saline solution into the protective tube (spiral) of the angioplasty stylet.
2. To introduce the angioplasty stylet into the lead, insert the flexible end of the stylet into the connector (using the funnel provided with the lead) and push it through the distal end of the lead.
3. Slide the angioplasty stylet through the lead several times to check that the tip seal is functioning properly.
4. Place the torquer on the angioplasty stylet.

## **INTRODUCING THE GUIDE CATHETER**

Please refer to the Information For Use (IFU) of the used Guiding catheter.

## **LEAD IMPLANTATION AND PLACEMENT**

1. When the lead has entered the coronary sinus, advance the angioplasty stylet.
2. Find the access and catheterize the target vein with the angioplasty stylet.
3. Hold the angioplasty stylet with one hand. With the other hand, push the lead along the angioplasty stylet.
4. When the lead is in the target vein, withdraw the angioplasty stylet.

**CAUTION:** *If a preliminary threshold test is done at this stage, completely retract the angioplasty stylet into the lead prior to the test (the stylet can alter the results).*

5. Affix the lead in the vein using one of the following two methods:

<b>Without screwdriver stylet</b>	Turn the lead body clockwise. The lead will screw into the vein. Do not exceed 8 turns.
<b>With SORIN screwdriver stylet</b> (contained in the re-intervention stylet kit)	Introduce the SORIN screwdriver stylet until it reaches the end of the lead. Turn the stylet clockwise to screw the lead into the vein. Then withdraw the stylet. Do not exceed 8 turns

**CAUTION:** *The SORIN stylets delivered with the Situs OTW lead or the Situs OTW stylet kit must be used. Using any other stylet may be hazardous to the patient.*

**COMMENTS:**

*Screwing advances the lead several millimeters into the vein.*

*If it is necessary to reposition the lead, first unscrew the lead (by rotating it counterclockwise) before withdrawing it.*

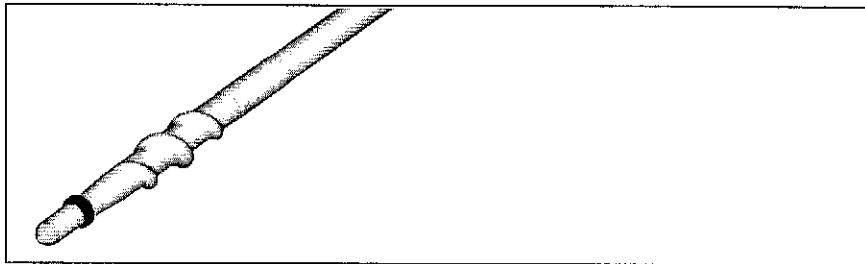


Fig. 2 – End of the lead with silicone fixation screw built into the lead body

## ELECTRICAL MEASUREMENTS

Check the electrosystolic pacing by taking the following electrical measurements:

1. High energy test (10 V) to confirm the absence of phrenic nerve stimulation.
2. Measure the pacing threshold.
3. Measure the sensed R-wave amplitude
4. Measure the impedance at 5 V (0.5 ms); standard values are between 500 and 1,500 Ohms.

**CAUTION:** *Always retract the angioplasty stylet completely into the lead before performing a threshold test (the stylet can alter the results).*

The threshold is measured with a battery-operated external cardiac impulse generator (follow the manufacturer's instructions for this device).

The following values should be obtained at the time of implantation:

Pacing Threshold	Amplitude of the Intracardiac signal
< 2.5 V at a pulse width of 0.5 ms	> 4 mV

## WITHDRAWING THE GUIDE CATHETER

Please refer to the Information For Use (IFU) of the used Guiding catheter.

## LIGATURE

The stylet must be completely withdrawn when fluoroscopy shows the lead is properly positioned and when electrical measurements are correct.

To prevent displacement of the electrode, it is recommended to clip and ligate the suture sleeve of the lead where it penetrates into the vein (Fig. 8). Tapered end must be introduced first in the vein.

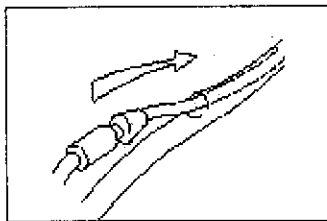


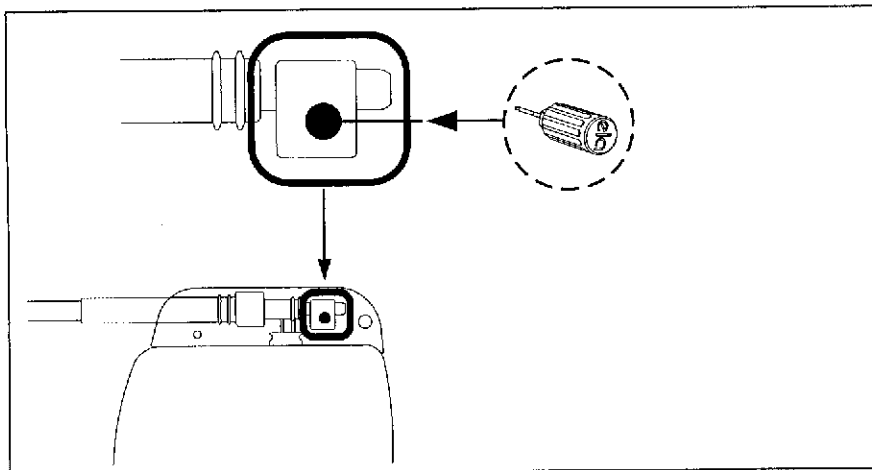
Fig. 8 - Ligature

**CAUTION:** do not ligate directly onto the insulating material of the lead, which could cause rupture of the insulation, leading to ineffective pacing.

**CAUTION:** leave a sufficient length when implanting the lead to allow for extension related to respiratory movements and cardiac contractions.

## INSERTING THE CONNECTOR INTO THE PULSE GENERATOR

1. Insert the IS-1 connector into the left ventricular port on the pulse generator.
2. Tighten the locking screw or screws (depending on the model).
3. Check the quality of the connection (the lead pin needs to go beyond the insert, see below).



## CONNECTIONS

SORIN leads comply with International Standard IS-1 and can be adapted to all pulse generators with IS-1/VS-1 connectors.

Unipolar leads possess a protective ring (false positive pole) on the proximal part of the connector allowing connection to a bipolar pulse generator.

Follow the instructions of the manual provided with the pulse generator concerning connection to the pulse generator.

## TECHNICAL SPECIFICATIONS OF THE LEAD

Total length		80 cm
Electrode	Material	Vitreous carbon
	Shape	Annular
	Surface area	4 mm <sup>2</sup>
	Steroid	Dexamethasone Sodium Phosphate
	Quantity of steroid	< 1.0 mg of Dexamethasone Sodium Phosphate
	Steroid collar	Silicone elastomer
Fixation		Silicone screw
Introducer size		7 F (2.33 mm)
Conductor	Material	MP35N
	Resistance	< 90 Ohms
Insulation	Material	Medical grade silicone rubber, polyurethane
	Diameter	Silicone: 4.8 F (1.6 mm)
		Polyurethane: 6 F (2 mm)
Connector		IS-1
Stylets furnished with lead		2 implant stylets
Pacing impedance measured according to Standard EN 45502-2-1:2003		500 - 1000 $\Omega$
Sensing impedance measured according to Standard EN 45502-2-1:2003		500 - 900 $\Omega$

## **LIMITATIONS OF GUARANTEE**

SORIN pays the utmost attention to the manufacturing of its cardiac leads and the related accessories. Because these are to be implanted in the human body, which is a very hostile environment to all implantations, sale of the leads and accessories manufactured and/or distributed by SORIN does not constitute any implicit or explicit warranty.

SORIN will in no case be held responsible for any expenses whatever the nature or damages directly or indirectly resulting from the acquisition, utilization, implantation, explantation or replacement of the leads or related accessories.





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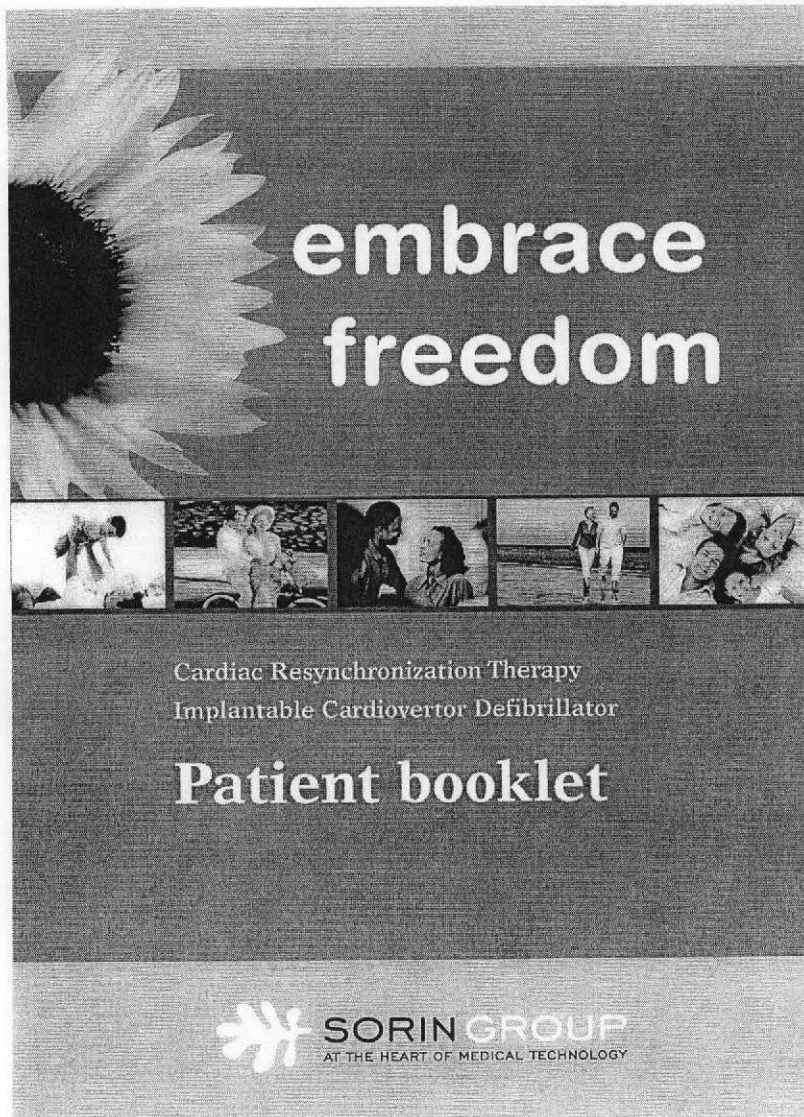
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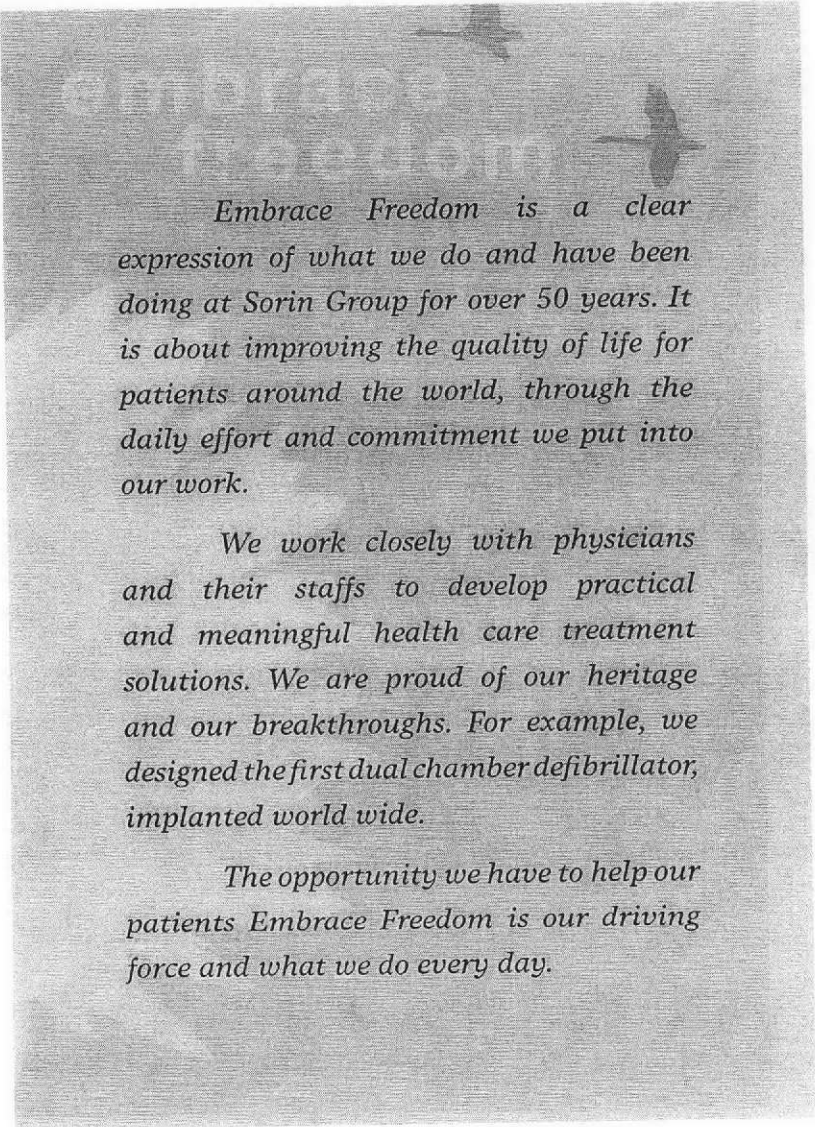
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*Embrace Freedom is a clear expression of what we do and have been doing at Sorin Group for over 50 years. It is about improving the quality of life for patients around the world, through the daily effort and commitment we put into our work.*

*We work closely with physicians and their staffs to develop practical and meaningful health care treatment solutions. We are proud of our heritage and our breakthroughs. For example, we designed the first dual chamber defibrillator, implanted world wide.*

*The opportunity we have to help our patients Embrace Freedom is our driving force and what we do every day.*

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## 1. Introduction

### 1.1. What is a CRT/ICD?

An implantable cardioverter defibrillator (ICD) with Cardiac Resynchronization Therapy (CRT) is a lifesaving device that is implanted in the upper chest area. It has a pacemaker and a defibrillator in it. It is about the size of a pager or a small child's palm. It is prescribed and implanted by a physician.

CRT is a therapy that consists of sending timely electrical pulses to the lower chambers of the heart. This allows the heart to beat in a more coordinated and synchronized manner, thus to beat more effectively.

An ICD automatically detects abnormal fast heart rhythms that may occur, and treats them by discharging an electric shock or rapid pacing to restore the normal rhythm.

A CRT/ICD is a device that combines these two types of therapies.

## INTRODUCTION

### 1.2. Why did my doctor recommend that I receive a CRT/ICD?

Your doctor has recommended that you have a CRT/ICD implanted because:

1. Your heart failure condition is associated with uncoordinated ventricular contractions.

A CRT/ICD is able to restore a coordinated contraction of your heart. By this action a CRT/ICD can improve the performance of the heart and improve symptoms associated with heart failure, such as breathlessness and lack of energy. Research has shown that many patients experience an overall improvement of their quality of life and increase in their capacity to perform day-to-day activities after the implant of a CRT/ICD.

2. Your heart condition exposes you to a risk of developing a dangerously rapid, heart rhythm. These abnormal rhythms can lead to cardiac arrest, a life threatening

## INTRODUCTION

event. Cardiac arrests require the help of doctors or emergency medical personnel in order to provide a shock (defibrillation) to restore the heart's normal rhythm. Cardiac arrest rarely gives any warning. Emergency medical personnel are often not immediately available. A CRT/ICD automatically provides the emergency therapy required to restore normal rhythm.

### 1.3. Are there alternative treatments?

#### ALTERNATIVE TREATMENTS FOR HEART FAILURE

After lifestyle and dietary changes as advised by your physician, the first line therapy for management of heart failure is most often medications.

Cardiac Resynchronization Therapy (CRT) pacemakers are available for the treatment of patients with moderate to severe heart failure. Cardiac Resynchronization Therapy pacemakers do not have the ability to treat abnormal fast rhythm (VT and VF) with rapid pacing or a defibrillation shock.



## INTRODUCTION

There are other non-pharmacological means of treating heart failure that may be discussed and advised by your physician. These may include surgical techniques to correct contributing factors such as a heart valve repair or replacement, temporary implant of a device to help the left ventricle pump better called a left ventricular assistance device, or heart transplantation.

### ALTERNATIVE TREATMENTS FOR LIFE-THREATENING ARRHYTHMIAS

A number of conditions, such as coronary heart disease or a previous heart attack, can put people at risk of life-threatening arrhythmias (abnormal heart rhythms). In some patients, the risk of arrhythmias can be completely eliminated or significantly reduced when the cause is treated (for example, by surgery or medication).

However for many patients, consideration of other procedures is not an option or the medications are not tolerated or effective enough. The protection given by an ICD or

## INTRODUCTION

CRT/ICD as determined by your physician may be the best treatment choice in managing your life-threatening arrhythmias.

### CONCLUSION

A CRT/ICD may treat your heart failure condition and provide the best protection against the risk of death from life threatening arrhythmias and cardiac arrest.

#### 1.4. Who should not receive a CRT/ICD?

CRT/ICD indications are based on medical research and your physician will determine whether or not you are indicated to receive this therapy.

Indications for consideration for patients with:

- Moderate to severe heart failure\*, when symptoms can not be managed by drugs or dietary regimen alone.
- A reduced heart pumping strength. A measure called "ejection fraction" should be found less than or equal to 35%.
- Uncoordinated ventricular contractions.

## INTRODUCTION

This can be observed through an abnormal finding on an electrocardiogram or EKG (QRS duration above 120ms), and/or during an echocardiography.

Heart failure patients that match the following description may not be indicated for CRT/ICD therapy as determined by their physician:

- Patients with mild heart failure, whose symptoms are well controlled by drugs
- Patients whose heart failure is not associated with disorganized ventricular contractions

\*Moderate to severe heart failure can be defined by:

- Significant or severe limitation in day-to-day activities due to heart failure symptoms (even very gentle activity)
- Symptoms experienced in all situations even at rest.

Heart failure symptoms severity is generally referred to as the New York Heart Association class. Moderate to severe heart failure corresponds to class III or IV.

## THE HEARTS AND ITS RHYTHMS

### 2. The heart and its rhythms

#### 2.1. Parts of the hearts

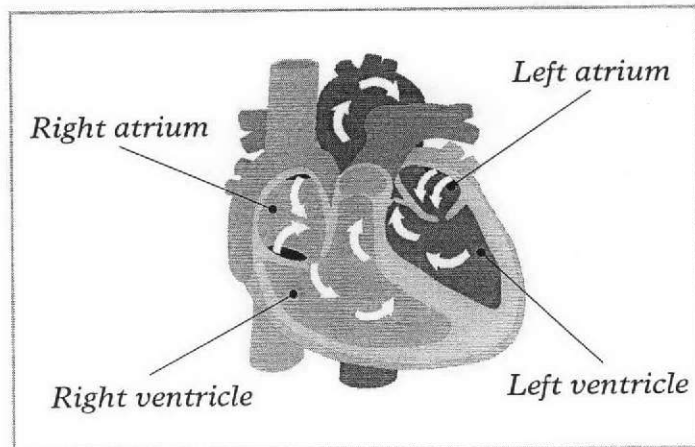
The heart is a pump that consists of four chambers separated by a wall and four valves. The two top chambers are called atria. They act like reservoirs. They collect and hold the blood until it can be moved to the main pumping chambers, the ventricles. The contraction of the atria and of the ventricles, in a coordinated sequence, make your heart pump blood to supply oxygen to your body.

Your heart is normally slightly larger than your clenched fist. Your heart is capable of beating over 100,000 times a day (at a rate of about 70 beats per minute). In one day it pumps more than 1,760 gallons (8,000 liters) of blood through approximately 11,800 miles (19,000 km) of circulatory system.



## THE HEART'S AND ITS RHYTHMS

*The right atrium collects "used" blood from all over your body. The right ventricle pumps the "used" blood to both lungs. The left atrium collects the newly oxygenated blood from your lungs. The left ventricle pumps the oxygen-rich blood back to feed the heart muscle itself and to the rest of your body.*



### 2.2. Heart Failure

Heart failure is a progressive condition affecting patients whose heart cannot pump

## THE HEARTS AND ITS RHYTHMS

enough blood to meet the needs of their body. Unlike other common cardiac disorders, such as heart attacks (myocardial infarctions or MI) or arrhythmias (abnormally fast or slow, or irregular cardiac activity), the heart does not suddenly lose its function, but, usually, weakens gradually over a period of time.

In early stages of heart failure, the heart and the vascular system (veins, arteries and capillaries) might compensate for the weakening of pumping activity, producing only mild to moderate symptoms.

Over time, this burden causes the heart to enlarge and heart muscles to weaken further, limiting the amount of blood that can be pumped throughout the body.

The contraction of the heart muscle can become disorganized, with different parts of the heart contracting at different times, thus reducing pump efficiency. A vicious cycle begins and symptoms worsen when the body cannot adjust to small additional burdens, such as light exercise. At this stage

## THE HEARTS AND ITS RHYTHMS

other organs become involved, with fluid accumulating in the lungs, feet and legs, and even the abdomen.

The causes of heart failure are multiple and can be present many years before symptoms develop. Damage to the heart muscle by a heart attack is a common starting point.

Other chronic conditions, such as high blood pressure, heart valve disease, diabetes, arterial disease, lung disease and familial causes are the main contributors.

### 2.3. Rhythm disturbances

#### NORMAL RHYTHM

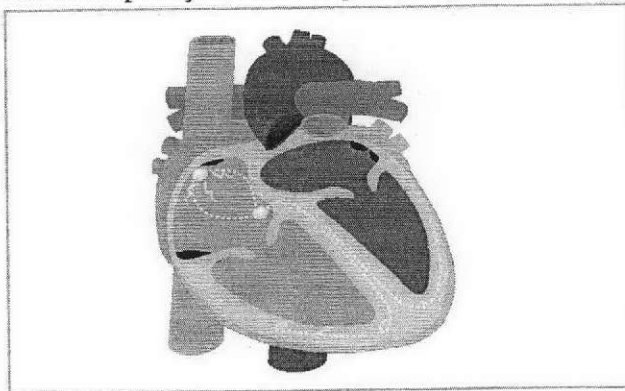
The normal rhythm is called sinus rhythm. Your own natural pacemaker, the sino-atrial (SA) node, is located in the right atrium.

Every second or less, this pacemaker fires, and an electrical signal spreads through the right and left atria, then continues down to the ventricles.

The normal rhythm of your heart can be disturbed in a number of ways.

## THE HEART'S AND ITS RHYTHMS

*An example of normal rhythm.*



*The electrical signal originates in the upper right atrium, propagates to the atria and reaches the ventricles. Both the right and left ventricles are activated at the same time. In response, the atria and ventricles can contract in a coordinated manner, to make the heart pump effective.*

### **BRADYCARDIA (SLOW HEART RHYTHM)**

Your heart normally beats between 60 and 80 times a minute. A rate lower than 60 beats per minute is normal only if you are



## THE HEARTS AND ITS RHYTHMS

resting, asleep, or very physically fit. A heart rate below 60 beats per minute is called bradycardia.

An abnormally slow heart rate or a very long pause between beats can cause tiredness, dizziness, and blackouts. When bradycardia is diagnosed in isolation, this condition is normally treated with a pacemaker. A CRT/ICD is also able to treat bradycardia, should this condition occur in conjunction with the CRT/ICD indication.

### TACHYARRHYTHMIAS

*(abnormal fast heart rhythms)*

If your heart rate is over 100 beats per minute this is called tachycardia. There are normal and abnormal fast heart rhythms. Exercise, mental or emotional stress, and some illnesses can cause your heart rate to rise normally, above 100 beats per minute.

When your heart rate is too fast, however, or occurs without cause, or is too fast and irregular, it is called a tachyarrhythmia.

The different types of tachyarrhythmia

## THE HEARTS AND ITS RHYTHMS

include Ventricular Tachycardia (VT) and Ventricular Fibrillation (VF), and are described below.

### **VENTRICULAR TACHYCARDIA (VT)**

VT is an abnormal rapid heart rate that originates in the ventricles. The heart pumps less blood with each beat because there isn't enough time for the chambers to refill with blood between beats. This causes symptoms such as dizziness, lightheadedness, near fainting symptoms, fainting, and loss of consciousness. For most patients, VT is dangerous if not treated.

### **VENTRICULAR FIBRILLATION (VF)**

In VF, the heart beats very fast and irregularly. This is due to chaotic electrical activity of the ventricles. Little or no blood is pumped. Your brain, heart and the rest of your body are quickly starved of oxygen.

Patients usually pass out within a few seconds. VF almost never stops on its own, and is therefore fatal unless the normal rhythm is restored with an electric shock to



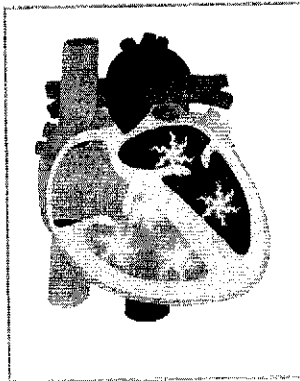
## THE HEARTS AND ITS RHYTHMS

“reset” the heart (defibrillation).

Defibrillation can be given by doctors or emergency medical personnel using paddles held to the chest (external defibrillation), or automatically by a CRT/ICD.

VT and VF have a number of causes, the most common of which is scarring of the heart due to a previous heart attack. Cardiac enlargement as a result of heart failure is also an important cause.

*An example of ventricular fibrillation. The electrical signal is not following the normal pathway. Instead, multiple pacemakers are firing at the same time. The heart can not contract properly, making the pump inefficient until a normal rhythm is restored.*



## DESCRIPTION OF THE CRT/ICD

### 3. Description of the CRT/ICD

Your CRT/ICD treats heart failure by continuously helping your heart to beat with more strength. It can also automatically recognize and stop abnormal heart rhythms, VT and VF.

#### 3.1. Parts of the device

##### **PULSE GENERATOR**

The pulse generator is a sealed titanium metal container about the size of a matchbox that contains electronic circuits, a memory and a battery.

By sending electrical pulses to both the right and left ventricles, the pulse generator helps the heart to beat more efficiently.

The pulse generator constantly checks your heart's natural electrical signals. If it detects an abnormal heart rhythm, it will convert it to a normal rhythm.

##### **LEADS**

The pulse generator is connected to the

## DESCRIPTION OF THE CRT/ICD

heart by three leads (insulated wires) that are threaded into the heart through veins, making their implantation a simple procedure. These leads allow the CRT/ICD to monitor your heart's rhythm, and deliver therapies (electrical pulses or shock) to your heart.

### PROGRAMMER

The programmer is a kind of computer, kept in the hospital or your doctor's office. It can communicate with the pulse generator by means of a wand that is held over the skin covering your pulse generator. It is used to test your CRT/ICD, program the treatments that your doctor wishes the CRT/ICD to use, and read the information stored in the memory between office visits.

### 3.2. How a CRT/ICD works

#### CARDIAC RESYNCHRONIZATION THERAPY

The normal contractions of the heart chambers (atria and ventricles) are precisely timed (or synchronized), and

## DESCRIPTION OF THE CRT/ICD

follow a strictly defined sequence. When this synchronization becomes disrupted, the amount of blood pumped with each beat is reduced, which is a cause of heart failure. A Cardiac Resynchronization Therapy (CRT) device paces the heart (using the same small electrical impulses as a standard pacemaker) both in the right and the left ventricles in order to resynchronize their contraction and attempt to increase the cardiac output. This therapy is also referred to as "Biventricular pacing".

In order to function properly, pacing leads (wires) must be placed in the right atrium, the right ventricle, and inside a cardiac vein to pace the left ventricle. All the leads can be implanted through the veins, without having to open the chest.

### TACHYARRHYTHMIA THERAPIES

Your CRT/ICD constantly checks your heart's electrical activity. It can tell whether the heart rhythm is normal, too slow, or too fast. If the rhythm is abnormal, an electrical

## DESCRIPTION OF THE CRT/ICD

treatment will automatically be given to your heart.

The kind of treatment will depend on the settings your doctor chooses. Your doctor will tell you which therapy he or she has programmed into your CRT/ICD.

VF can be an immediate life-threatening situation. The CRT/ICD is designed to deliver a shock in order to restore the heart's normal rhythm. This is called defibrillation. Your CRT/ICD can also deliver other types of therapy to treat abnormal heart rhythms, Anti-tachycardia pacing, and Anti-bradycardia pacing.

### DEFIBRILLATION

If your CRT/ICD detects VF, it delivers a high-energy shock. This is called defibrillation. Because the shock is given directly to the heart, the strength required is only about 1/10th of that given when doctors or emergency medical personnel place paddles on the chest. The total time from the start of VF to the shock itself is usually around 10

## DESCRIPTION OF THE CRT/ICD

seconds. This is the amount of time it takes for the CRT/ICD to accumulate energy in the pulse generator so that a big shock can be given. Fainting from the VF is not uncommon during the time it is charging.

### ANTI-TACHYCARDIA PACING

When VT is detected, the CRT/ICD checks if the rhythm should be treated. If the doctor has programmed this treatment, the CRT/ICD gives a short burst of small, rapid electrical pulses to interrupt the arrhythmia. This is called Anti-Tachycardia pacing. You may not even feel these pulses.

### ANTI-BRADYCARDIA PACING

Your CRT/ICD can act as a pacemaker, to prevent your heart from beating too slowly. CRT/ICDs can sense and pace the atria and the ventricles to ensure a proper heart rate.



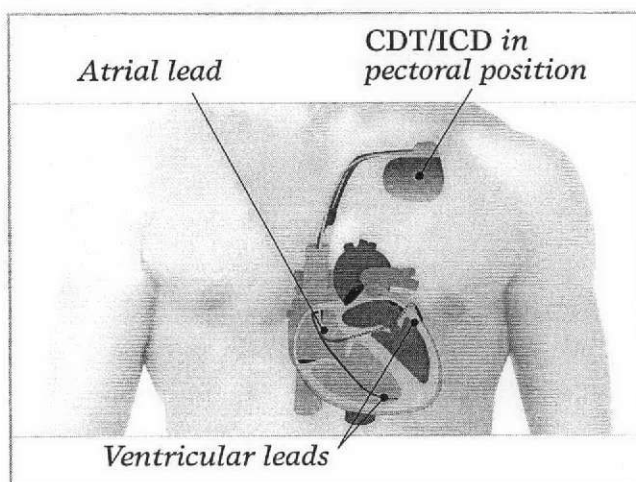
## DESCRIPTION OF THE CRT/ICD

### 3.3. Implantation procedure

The operation to implant a CRT/ICD is usually performed under heavy sedation or occasionally general anesthesia. Your doctor will discuss this with you. The pulse generator will most commonly be implanted in your chest. Your doctor will first make an incision in the skin. Your doctor will then make a "pocket", either under the skin or under the muscle, in which to place the pulse generator. The three leads are then passed through a vein and positioned in chambers of your heart.

The position is checked by x-ray, and the leads are tested to ensure that they are in good contact with the heart. The leads are connected to the pulse generator, which is then placed in the pocket. Before the incision is closed, your doctor will perform different tests to check the proper connection of your CRT/ICD system.

## DESCRIPTION OF THE CRT/ICD



### 3.4. At hospital discharge

Your doctor will tell you whether you have skin stitches which dissolve in time, or whether the stitches will need to be removed later in an office visit. The wound and the pocket under the skin will be rather sore for a few days.

Always follow your doctor's directions while you recover and begin to resume normal activities. Some suggestions that will help in

## DESCRIPTION OF THE CRT/ICD

your recovery:

- Bathe, exercise, and walk according to your doctor's instructions.
- Don't lift anything heavy (more than 10 or 15 pounds) until your doctor gives the OK.
- Limit arm movements that could affect the leads, if your doctor has instructed you to.
- Don't wear tight clothing that may irritate the skin over the pulse generator.
- Avoid any activity or contact sport that could result in a blow to your implant. These include, but are not limited to, karate, football, tennis, golf, or placing a shotgun or rifle against the side of the chest your device is implanted.

Be sure to tell all your doctors, dentists or any emergency personnel that you have an implant.

**WARNING:** Tell your doctor immediately if there is redness, swelling, warmth, or drainage from your incisions. This may indicate an infection which could be serious.

## DESCRIPTION OF THE CRT/ICD

Contact your doctor if your arm becomes swollen or if pain persists after the initial healing of your incision, or if you develop a fever that does not go away in two or three days. Pain can also indicate the need to contact your physician as soon as possible.

### 3.5. Follow-up visits

After implant, it is normal that you continue to see your regular physician, cardiologist, and heart failure specialist for overall management of your condition and to follow-up on the functioning of your CRT/ICD. Your doctor will use the programmer to “talk” with the CRT/ICD.

He/she will:

- Check that the leads are working well,
- Check that Cardiac Resynchronization Therapy is delivered correctly,
- Check the battery to see how much energy is left, and
- Find out if the CRT/ICD has treated any arrhythmias.

## DESCRIPTION OF THE CRT/ICD

Your doctor will also ask you which drugs you are taking and check if there are any interactions with your CRT/ICD.

He or she will also check to see if your heart condition has changed since your last visit. Depending upon your condition and the information retrieved from the CRT/ICD, your doctor may wish to "fine-tune" some of the CRT/ICD's settings. Your doctor will use the programmer to make any of these changes. Your doctor will give you a schedule to follow for these follow-up visits.

### 3.6. Unit replacement

The batteries in your CRT/ICD should last for a number of years. They wear down very gradually and predictably. Several months before the batteries are expected to run down, your doctor will tell you that your pulse generator must be replaced. In an operation much like the original implant, your scar will be opened and the old pulse generator removed (it is a sealed unit, so the batteries cannot be replaced separately). The leads

## DESCRIPTION OF THE CRT/ICD

will also be tested. They are then connected to a new pulse generator and then the pocket is closed.

Occasionally, leads need to be replaced. Lead replacement procedures can be more complex procedures, similar to the initial implant procedure. Ask your doctor for more information.

## WARNINGS AND PRECAUTIONS

### 4. Warnings and precautions

- ☞ **WARNING:** Tell your doctor immediately if there is redness, swelling, warmth, or drainage from your incisions. This may indicate an infection which could be serious. Contact your doctor if your arm becomes swollen or if pain persists after the initial healing of your incision, or if you develop a fever that does not go away in two or three days. Pain can also indicate the need to contact your physician as soon as possible.
- ☞ **WARNING:** Follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets. These types of equipment may interfere with your CRT/ICD and temporarily prevent a normal functioning.
- ☞ **WARNING:** Always walk briskly through security gates in stores, libraries, and

## WARNINGS AND PRECAUTIONS

airports. Security detectors may cause temporary interference with your CRT/ICD and prevent a normal functioning.

☞ **WARNING:** Avoid activities likely to cause a blow to the skin over the CRT/ICD. This would not normally damage the device, but could injure the tissues lying over it.

☞ **WARNING:** Magnetic resonance imaging (MRI) is not recommended for any patient with a CRT/ICD under any conditions. Because the equipment uses such powerful magnets, avoid even entering any room with MRI equipment - no matter what the reason. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.

☞ **WARNING:** Make sure others know that they should dial the emergency number immediately if you remain unconscious for more than one minute after a shock



## WARNINGS AND PRECAUTIONS

treatment.

- ⚠ **WARNING:** Make sure others know that they should call your doctor if you don't feel well after shock treatment, even if you regain consciousness. Give them your doctor's phone number ahead of time.

Other Warnings and Precautions are listed in some specific sections of this document. Please refer to these sections whenever you are seeking for information.

## LIVING WITH YOUR CRT/ICD

### 5. Living with your CRT/ICD


#### 5.1. Your CRT/ICD identification card

You will be given a card when you leave the hospital. Always carry your CRT/ICD identification card with you when you go out, even for a quick errand. Your card has important information about your CRT/ICD and leads, and your doctor's name and phone number.

It also has important information for emergency medical personnel, if treatment is necessary. If you move, change your phone number, or change doctors, tell your doctor you need a new CRT/ICD identification card. Or, you can contact ELA Medical Inc Patient/Device Tracking directly (see "User Assistance Information" section at the end of this booklet).

## LIVING WITH YOUR CRT/ICD

Example of the CRT/ICD identification card:

<b>IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR (ICD) CARD</b>  <b>SORIN GROUP</b> <small>OF THE HEART OF MEDICAL TECHNOLOGY</small> 14401 West 62nd Way, Denver, CO 80044 - 3000 Tel: 877-ONE-SORIN / 877-663-7674 Fax: 303-555-6999		<b>MANUFACTURED BY: SORIN</b> <b>IMPLANT DATE</b> <b>MAGNET RATE</b> NO. Model Serial AICD M.S. Model Serial M.S. Model Serial VNS Model Serial M.S. Model Serial M.S. Model Serial
<b>PATIENT NAME</b> _____ <b>ADDRESS</b> _____ _____ <b>PHONE</b> _____		<b>PHYSICIAN TO NOTIFY IN EMERGENCY</b> <b>NAME</b> _____ <b>ADDRESS</b> _____ _____ <b>PHONE</b> _____

### 5.2. Activities and exercise

Your doctor may advise you to avoid activities where a few seconds of dizziness or unconsciousness could be dangerous to you or others. These activities might include:

- Driving a car,
- Swimming or boating alone, or
- Climbing a ladder.

Your doctor will tell you if you can start driving again. This will be determined by the laws in your state and by your medical

## LIVING WITH YOUR CRT/ICD

condition. Contact your physician if you experience any dizziness, blackouts, or loss of consciousness.

Patients with a CRT/ICD automatically lose their right to pilot an airplane because of their underlying heart condition.

Always follow your doctor's recommendations about resuming your normal daily activities. Such activities may include:

- Returning to your job,
- Resuming sexual activity,
- Travel, and
- Exercise, recreation, or other hobbies.

### RETURNING TO YOUR JOB

Your CRT/ICD should not affect your ability to work, except under special circumstances. Because jobs and workplaces vary, there is no single answer. Be sure to tell your doctor if you use or must come near:

- High voltage electrical equipment,
- Strong magnets, like those used in the steel or auto scrap industry,

## LIVING WITH YOUR CRT/ICD

- Radar, or
- Other sources of strong electromagnetic interference.

Tell people at work that you have a CRT/ICD and what they should do if you receive a shock (see section 5.4).

If you have any questions about your work or workplace, ask your doctor.

### SEXUAL RELATIONS

Your CRT/ICD should not interfere with sexual intimacy. If you receive a shock treatment while someone is in contact with you, they may feel it but it should not harm them.

### TRAVEL

Your CRT/ICD should not prevent you from traveling. Check with your doctor for specific advice before planning any trip that would make it difficult for you to come back within one day.

Remember to:

## LIVING WITH YOUR CRT/ICD

- Take along this manual, if you or emergency medical personnel have any questions.
- Ask your doctor for the name of a doctor or heart clinic in the city, state, or country you will be visiting.

If an emergency occurs, you will be prepared to seek help.

- Always show your CRT/ICD identification card at security checkpoints, such as airports. Ask for a hand search without a hand-held screening wand. Security detectors are unlikely to cause problems if you walk through the "gate" without lingering.
- Ask your doctor to arrange a follow-up visit with a doctor in the area you will be visiting if you will be away for more than six months.

### EXERCISE, RECREATION, AND OTHER HOBBIES

Exercise is good for the heart, and you are encouraged to lead an active life. You should discuss with your doctor what kind of exercise program is best for you. A small number of

## LIVING WITH YOUR CRT/ICD

sports should be avoided:

- Contact sports (such as karate or football)
- Deep sea diving
- The butt of a shotgun or rifle should not be held against the side of your chest where the CRT/ICD is implanted.

**⚠ WARNING:** Avoid activities likely to cause a blow to the skin over the CRT/ICD. This would not normally damage the device, but could injure the tissues lying over it.

Avoid direct sun exposure to the skin over your implant. Be sure to wear at least a T-shirt or other clothing to shield this area.

The following activities will not cause problems to your CRT/ICD but may be of concern because of your medical condition. You should discuss possible heart risks with your doctor regarding:

- Snorkling, and
- Shallow scuba-diving.

## LIVING WITH YOUR CRT/ICD

### 5.3. When to call your doctor

Your doctor will give you instructions about when you should call him or her. In general, you may be asked to call if you:

- Receive a shock or any other therapy from your CRT/ICD
- Have symptoms of an abnormal heart rhythm.
- Notice any swelling, redness, warmth, or drainage from any incision.
- Have any questions about your CRT/ICD, heart rhythm, or medications.
- Plan to travel or move.
- Notice anything unusual, such as new, unexplained symptoms or symptoms like those you had before you received your CRT/ICD.

### 5.4. What to do if you receive a shock treatment

If you begin to feel symptoms of a fast heart rate, your CRT/ICD will probably deliver therapy within a few seconds.

Your physician will discuss this with you and



## LIVING WITH YOUR CRT/ICD

give you specific instructions on what to do if you receive a shock. These may include:

1. You should stay calm. Find a place to sit or lie down.
2. If possible, ask someone to stay with you throughout the event. If someone is touching you when the CRT/ICD delivers a shock, they should feel little more than a tingle, as the device is designed to focus its current on your heart, not elsewhere.  
It will not harm anyone touching you. They might also feel your muscles become tense or see you "jump" slightly, as if startled.
3. Have a friend or family member phone the emergency number if you remain unconscious for more than one minute.
4. If you are conscious but do not feel well after shock therapy, have someone call your doctor immediately.  
Follow your doctor's orders. You may be told to come to the emergency room.
5. If you feel fine after therapy and symptoms

## LIVING WITH YOUR CRT/ICD

do not reappear, you may not need to seek medical help immediately.

Follow your doctor's instructions on when to call after receiving a shock. When you do call, your doctor or a nurse may ask you the following questions:

- What were you doing right before shock therapy?
- What symptoms did you notice before shock therapy?
- How did you feel right after shock therapy?

It is important to plan ahead with your family and friends for contacting emergency medical personnel and your doctor. The section "User Assistance Information" at the end of this manual has space for your local emergency phone numbers and information about your current medications. Keep a copy of this information next to your phone so anyone can see it easily if an emergency occurs.

## MAGNETIC INTERFERENCE

### 6. Electromagnetic interference

Anything that uses electricity, is powered by batteries, or contains magnets has an electromagnetic field around it.

For most household appliances, these fields do not cause any problem to your CRT/ICD. This is because the field is very weak to begin with. It is also because the strength of an electromagnetic field decreases very rapidly, even with a small distance. However, a very strong electromagnetic field could interfere with your CRT/ICD; this is called electromagnetic interference (EMI).

**⚠ WARNING:** Follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets. These types of equipment may interfere with your CRT/ICD and temporarily prevent a normal functioning.

Strong EMI can keep your CRT/ICD from delivering the right treatment to your heart

## MAGNETIC INTERFERENCE

in case of abnormal heart rhythm. It can even cause your CRT/ICD to give you an inappropriate shock. The effect usually lasts only while you are near the source of strong EMI. Move away and the normal function of your CRT/ICD will usually return once the EMI stops. In rare cases, really strong EMI can permanently damage your CRT/ICD's circuits or change the programmed settings.

### **6.1. Safe household appliances, tools and other equipment**

Your CRT/ICD has been built to protect it from interference by most electrical appliances. The following are safe to operate if they are in good repair and properly grounded (if required):

- Microwave ovens,
- Televisions, AM/FM radios, video cameras, VCRs, and their remote controls,
- Garage door openers,
- Countertop appliances, such as toasters, blenders, food processors, electric knives, electric can openers, etc.

## MAGNETIC INTERFERENCE

- Hand-held appliances, such as hair dryers, shavers, curling irons, etc.
- Major appliances, such as washers, dryers, electric stoves, refrigerators and freezers, dishwashers, etc.
- Electric blankets and heating pads,
- remote-controlled transmitters for toy cars and airplanes.
- Personal computers and printers,
- Electric typewriters, fax machines, and copy machines,
- Low-power radio transmitters, such as cordless telephones or walkie-talkies.

Also safe to use are:

- Spark-ignited internal combustion engines, such as those in lawn mowers, leaf-blowers, and automobiles (if your doctor has not restricted your right to drive),
- Battery-operated conveyances, such as golf carts or electric wheelchairs.

## MAGNETIC INTERFERENCE

### 6.2. Equipment that may not be safe to use

#### CELLULAR PHONES

Digital cellular phones can cause EMI if they are very close (within 6 to 12 inches) to the CRT/ICD. The effect is temporary. To avoid interference:

- Don't carry a cellular phone in a breast pocket on the same side as the pulse generator, if it is implanted in your chest.
- Hold the cellular phone to the ear on the opposite side of your body from the pulse generator.

#### SECURITY DETECTORS

Security detectors used in stores and libraries are unlikely to cause problems if you walk through the "gate" without lingering. Do not stand close to the outside of the detection equipment. If you have any concern, show your CRT/ICD identification card and ask that the detector be turned off while you walk through.

## MAGNETIC INTERFERENCE

The security detectors (both walk-through and handheld wands) used in airports and government buildings may cause temporary interference with your CRT/ICD.

The metal case of your pulse generator may set off security alarms. Present your CRT/ICD identification card to security personnel and ask for a hand search. It is important that security personnel understand that a search with a handheld wand should be avoided.

☞ **WARNING:** Always walk briskly through security gates in stores, libraries, and airports. Security detectors may cause temporary interference with your CRT/ICD and prevent a normal functioning.

### OTHER EQUIPMENT

The following may be sources of EMI. Keep them at least 12 inches away from your CRT/

## MAGNETIC INTERFERENCE

### ICD:

- Running car engines (sparks can cause EMI and some alternators contain strong magnets),
- Electric motors, if running,
- Machine shop tools, such as electric drills, circular saws, table saws, etc.
- Furnaces,
- Hot water heaters.

**⚠ WARNING: Do not use body-fat monitors designed for home use. This equipment may cause temporary interference with your CRT/ICD.**

The following may be sources of strong EMI. Keep them at least 24 inches away from your CRT/ICD:

- Stereo speakers in large stereo systems, large radios
- Strong magnets,
- Industrial equipment such as power generators and arc-resistance welders,
- Battery-powered cordless tools, such as drills, screwdrivers, etc.





## MAGNETIC INTERFERENCE

- Antennas used for medium power radio transmitters, such as ham or CB radio, long-distance radio, or satellite telephones,
- High-power loudspeakers (such as those found in public buildings).

The following are sources of very strong EMI.

Keep away from:

- Any radar equipment,
- Large TV or radio transmission towers,
- Power lines carrying more than 100,000 volts.

⚠ **WARNING:** Keep away from high power equipments like power lines, radar, large TV or radio transmission towers. These equipments may cause interference with your CRT/ICD. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.

### 6.3. Medical and dental procedures

Most medical and dental procedures will not interfere with your CRT/ICD. These procedures include:

## MAGNETIC INTERFERENCE

- Diagnostic x-rays, such as chest, dental, CT scans, and mammography,
- Dental procedures to clean or repair teeth.

Some procedures can be carried out with proper precautions (the equipment should not be placed directly over the pulse generator):

- Transcutaneous electrical nerve stimulation (TENS).

Other medical procedures or devices produce a high level of interference that could seriously affect the function of your CRT/ICD. Be sure to discuss their risks and benefits with your doctor. These include:

- Lithotripsy (the use of shock waves to break up kidney and gall stones inside your body),
- Electrocautery (this is an electronic device used to stop bleeding during surgery),
- Diathermy (this equipment uses an electric field to apply heat to tissues, such as muscle),

## MAGNETIC INTERFERENCE

- Radiation therapy,
- Therapeutic ultrasound.

**CAUTION:** Always tell all medical personnel that you have a CRT/ICD. Some medical procedures or devices may cause temporary interference with your CRT/ICD and prevent a normal functioning.

**⚠ WARNING:** Magnetic resonance imaging (MRI) is not recommended for any patient with a CRT/ICD under any conditions. Because the equipment uses such powerful magnets, avoid even entering any room with MRI equipment - no matter what the reason. The circuits of your CRT/ICD could be permanently damaged or the programmed setting changed.

## QUESTIONS YOU MAY HAVE

### **7. Some questions your may have about your ICD**

#### **7.1. Should I be worried about my CRT/ICD?**

A CRT/ICD is meant as an aid to live a normal life, helping to overcome the symptoms of heart failure, and eliminating the constant fear of consequences of untreated cardiac arrest. For some patients, the CRT/ICD itself can become a focus of worry. Remember that it was given to you with the hope of helping you feel better and to protect you from tachyarrhythmias. CRT/ICDs are extremely reliable - they save lives every day. It is best to bring your worries into the open by discussing them with your doctor, your family, or possibly a support group.

#### **7.2. Will I experience pain, or a big lump under the skin?**

After the initial healing of the wound, the area around your CRT/ICD should be



## QUESTIONS YOU MAY HAVE

painless. However, it is quite common for patients to remain "aware" of its presence under the skin.

In the same way, once the incision has healed, all that should be visible is a bulge under the skin, and this cannot be seen when a shirt or blouse is worn.

**CAUTION:** Check with your doctor if pain persists after the initial healing of your incision.

### **7.3. Will the CRT/ICD cure my heart disease?**

Heart failure is a progressive disease. Its evolution can be influenced by appropriate treatment, but unfortunately a cure is very uncommon.

While CRT may reduce many of your symptoms and make you feel considerably better because your heart is pumping blood more efficiently, your heart failure is still present and needs to be managed carefully by your doctor. Consult your doctor before

## QUESTIONS YOU MAY HAVE

you begin any new activities and follow his or her advice.

### **7.4. Will I need to take medication?**

Medication is the first course of treatment for heart failure condition. Do not stop taking drugs prescribed by your heart failure doctor. The CRT/ICD does not affect the need for these medications, but it does not interfere with them either.

Even though the CRT/ICD can treat ventricular arrhythmias very successfully, it cannot prevent them from occurring. Some patients, therefore, take medication to reduce the frequency of arrhythmias and prevent the CRT/ICD from firing too often.

### **7.5. What will happen when the CRT/ICD “fires”?**

The CRT/ICD can give a number of different treatments. Cardiac Resynchronization Therapy, as well as Anti-Bradycardia pacing, are not felt at all.

Brief awareness of a rapid heart beat may

## QUESTIONS YOU MAY HAVE

occur right before Anti-Tachycardia pacing. Some people report a defibrillation shock as feeling like a small jolt, others like a kick in the chest. Either way, the discomfort is momentary and there are no after-effects. Of course, the arrhythmia that triggers the device may make you feel a very rapid heart beat, dizziness or even fainting. Ventricular fibrillation causes most people to black out or faint within a few seconds, so that they are not aware of the shock when it occurs.

### **7.6. What should I tell to my family and friends?**

You should tell your family, friends, and co-workers about your CRT/ICD. They should know that if the device fires, they do not need to do anything other than to make you comfortable while you recover.

If someone is touching you when the CRT/ICD gives a shock, they should feel little more than a tingle, as the device is designed to focus its current on your heart, not elsewhere. It will

## QUESTIONS YOU MAY HAVE

not harm anyone touching you. They might also feel your muscles become tense or see you "jump" slightly, as if startled.

Some friends and family members may want to learn cardiopulmonary resuscitation. This can be arranged through your local Red Cross chapter.

☞ **WARNING:** Make sure others know that they should dial the emergency number immediately if you remain unconscious for more than one minute after a shock treatment.

☞ **WARNING:** Make sure others know that they should call your doctor if you don't feel well after shock treatment, even if you regain consciousness. Give them your doctor's phone number ahead of time.



## SUMMARY

### 8. Summary

This section is a reminder of some general considerations when living with a CRT/ICD. It is not meant to replace reading the complete instructions found in this booklet.

Your doctor may have recommended that you have a cardioverter-defibrillator with cardiac resynchronization therapy implanted (CRT/ICD).

This is because your doctor believes you are at risk of developing a dangerous heart rhythm that can be treated with this device.

If you are implanted with a CRT/ICD, follow all warnings concerning pacemaker patients, such as those in airports, near high voltage sources, and near extremely strong magnets.

Your doctor has already discussed with you any precautions you need to take to protect your implant from damage. Follow these instructions very carefully.

Always follow your doctor's recommendations about resuming your normal daily activities.

## SUMMARY

These may include:

- Returning to your job,
- Returning to sexual activity,
- Travel, and
- Exercise, recreation, or other active hobbies.

Your doctor will give you instructions about when you should call him or her. In general, call your doctor if you:

- Receive a shock or any other therapy from your CRT/ICD and have been told to call,
- Have symptoms of an abnormal heart rhythm and have been told to call,
- Notice any swelling, redness, warmth, or drainage from any incision.

## GLOSSARY

### 9. Glossary

**Anti-Tachycardia pacing (ATP):**

Some tachycardias can be interrupted by rapid pacing of the heart. Modern CRT/ICDs can be programmed to use Anti-Tachycardia pacing to stop an episode of ventricular tachycardia, avoiding the need for a high-energy shock.

**Arrhythmia:**

An abnormal heart rhythm.

**Atrioventricular (AV) node:**

A specialized part of the heart that is normally the only electrical connection between the atria and the ventricles.

If the AV node does not function properly, your CRT/ICD can take over by pacing the ventricles in the right rhythm with the atrium.

**Atrium/Atria:**

The left and right atria are the upper chambers of the heart.

The right atrium pumps blood into the right

## GLOSSARY

ventricle. The left atrium pumps blood into the left ventricle.

**AV node (see Atrioventricular node)**

**Bradycardia:**

A heart rate less than 60 beats per minute. This can be quite normal while at rest or sleeping, or in especially physically fit people. It may also be caused by the sinoatrial node working too slow or blockage of the electrical pathways in the heart. (See sinoatrial node)

**Cardiac arrest:**

During cardiac arrest the heart stops completely.

**CRT (Cardiac Resynchronization Therapy):**

CRT is a heart failure therapy that consists of sending timely electrical pulses to the lower chambers of the heart in order for the heart to beat in a more coordinated and synchronized manner, thus beat more effectively.

**CRT/ICD:**

Device that combines Cardiac Resynchronization Therapy and protection against life-threatening rhythms, by

## GLOSSARY

delivering anti-tachycardia therapy or shocks, as needed.

**Defibrillation:**

Stopping ventricular fibrillation with an electric shock.

This can be achieved by medical personnel at the scene of a cardiac arrest, using paddles placed on the chest, or automatically by a device implanted in the chest (an ICD or CRT/ICD).

**Defibrillator:**

An external or implanted device that can deliver a shock to the heart. It is used to treat abnormally fast and irregular heart rhythms.

**ECG/EKG:**

Electrocardiogram. A printout of the electrical activity of the heart.

**Electrocautery:**

A procedure that uses electricity to stop bleeding during surgery.

## GLOSSARY

**Electromagnetic field:**

This is an invisible area of energy. It is found around magnets. It also occurs when electricity is used, both around devices plugged into an outlet and those that are battery-powered.

**Electromagnetic interference:**

If an electromagnetic field is very strong, it can interfere with your CRT/ICD. It can prevent your CRT/ICD from giving you the right treatments or it can even cause your CRT/ICD to give you an inappropriate shock.

**Fibrillation:**

Rapid, irregular beating of the atrium or ventricle. (See Ventricular fibrillation).

**Heart attack:**

If an artery that carries blood to the heart muscle becomes blocked, the muscle is starved of oxygen. Some of your heart tissues die as a result. A previous heart attack is one of the more common causes for ventricular

## GLOSSARY

arrhythmias that require treatment with an ICD or CRT/ICD. The medical term for a heart attack is a myocardial infarction.

**Heart failure:**

Weakness of the heart muscle. This can cause many symptoms, including breathlessness, dizziness, tiredness, and the accumulation of fluid in the lungs, abdomen, and legs.

**ICD:**

An implantable cardioverter defibrillator. An ICD is an implanted device that can deliver pacing for slow heart rhythms, rapid pacing (Anti-Tachycardia pacing), or a shock to the heart to treat fast abnormal heart rhythms and restore normal rhythm.

**Implantable cardioverter defibrillator**  
(see ICD)

**Myocardial infarction (see Heart attack)**

**Pacing:**

Stimulation of the heart by small electrical impulses. Pacemakers are used to treat slow heart rates. ICDs and CRT/ICDs use pacing

## GLOSSARY

to treat slow heart rates (bradycardia).

**Programmer:**

Equipment kept in your doctor's office that communicates with your CRT/ICD when you come for a checkup. The programmer can "read" a great deal of information stored in the CRT/ICD's memory. It reports the status of the battery and leads, the rhythms and rates of your heart since your last visit, and any therapies your CRT/ICD has given. The programmer can then be used to program your CRT/ICD, setting the therapies that your doctor has selected for the treatment of slow and fast heart rates.

**Pulse generator:**

The main part of a pacemaker, ICD or CRT Device. It is the sealed unit containing the battery, microprocessor (minicomputer), memory and electronic components. When a pacemaker, ICD or CRT device's battery is running down, the entire pulse generator is replaced.



## GLOSSARY

**SA node (see Sinoatrial node)**

**Sinoatrial (SA) node:**

This is a small group of cells in the right atrium that sends electrical signals that make the heart beat.

**Sudden cardiac death:**

Death due to an electrical problem in the heart. It is usually caused by ventricular fibrillation or ventricular tachycardia. A CRT/ICD can greatly lower the risk of sudden cardiac death.

**Tachycardia:**

A heart rate usually greater than 100 beats per minute. It can be a normal response to exercise, stress, or illness.

**Tachyarrhythmia:**

Any disturbance of the heart's rhythm, regular or irregular, resulting in a rate over 100 beats per minute without a normal cause for tachycardia.

**Ventricles:**

The left and right ventricles are the main

## GLOSSARY

pumping chambers of the heart. They receive blood from the left and right atria, and pump it to the body and the lungs.

**Ventricular fibrillation (VF):**

An arrhythmia causing an abnormally rapid and irregular beating of the ventricles. Because the heart pumps little or no blood, this arrhythmia is fatal unless a shock is given (defibrillation) to restore normal rhythm.

**Ventricular tachycardia (VT):**

An arrhythmia causing an abnormally rapid but regular beating of the ventricles. This can cause anything from mild symptoms of dizziness to fainting. If untreated ventricular tachycardia can lead to ventricular fibrillation.

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## USER ASSISTANCE INFORMATION

*(Ask your doctor or nurse to complete the information on this page before you leave the hospital.)*

**ELA Medical Inc Patient/Device Tracking**  
**Toll-free number: 1-877-ONE-SORIN (1-877-663-7674)**  
**Facsimile: 1-866-500-6096**

**Emergency Medical Assistance:**

**Name / Address / Phone Number of your cardiologist:**

**ICD:**

Type/Model Number

Date Implanted

**Atrial Lead:**

Type/Model Number

Date Implanted

**Right Ventricular Lead:**

Type/Model Number

Date Implanted

**Left Ventricular Lead:**

Type/Model Number

Date Implanted

**Name/Address/Phone Number of Hospital:**

**Current Medications:**

**Name/Phone Number of Relatives:**



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